Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

**PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS**

(submitted by the evaluating Competent Authority)



DX3 GEL

Product type 18

Imidacloprid

Case Number in R4BP: BC-EX038637-07

Evaluating Competent Authority: FR

Date: [January 2020]

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**Note to the reader**

This consolidated PAR of the product authorisation DX3 GEL is based on the PAR of the first authorisation for DX3 GEL, granted by France (FR) on 2020, in which all necessary addenda have been included.

In the following assessment report of this consolidated PAR, each section contains the initial assessment and the subsequent successive assessments (minor change, major change, post-authorisation data…). The assessments related to the post-authorization data of the product are at the end of each concerned section and are highlighted in grey.

**History of the dossier**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Application type** | **refMS** | **Case number in the refMS** | **Decision date** | **Assessment carried out (i.e. first authorisation / amendment /renewal)** |
| NA-APP | *FR* | BC-EX038637-07 | 09/03/2020 | National authorisation |
| Post-AMM | *FR* | - | - | Post-authorisation data assessment |

# CONCLUSION

***Intended uses***

*DX3 GEL product is type of product 18 for ant control based on 0.02% of imidacloprid. It is a gel-ready-to use bait (gel only or gel in bait boxes) used by general public and professional users for ant control. It is intended to be applied indoor, outdoor (crack and crevice, around building or near entrances).*

***Conclusion of the physico-chemical and technical properties***

The appearance of the product is a colourless gel with characteristic odour. There is no effect of high temperature on the stability of the formulation, since after 2 weeks at 54°C (when stored in LDPE syringes, HDPE syringes, PP cartridges and bait boxes) and 12 weeks at 35°C (when stored in PP syringes), neither the active ingredient content nor the technical properties were changed.

The low temperature stability test was not performed. Thus, the product must be protected from frost.

The product must be protected from light.

The accelerated storage of the product indicates that the biocidal product is expected to be stable 2 years at ambient temperature. However, a long term storage stability study (on-going) is needed to prove the stability of the product in post-authorization. The product is not flammable. It has no explosive and no oxidizing properties.

The product is not classified with regard to physical and chemical properties.

A full CLP data package will be required for renewal of the product. This is particulary relevant for self reactive and corrosion to metal properties.

The analytical method is fully validated for the determination of the active substance Imidacloprid in the product. Analytical methods were provided at EU level for the determination of Imidacloprid residue in soil, water and air. An analytical method in biological matrices is not required. The product is not intended to be used on surface in contact with food/feed of plant and animal origin, analytical method for the determination of Imidacloprid in food/feed of plant and animal origin is not required.

***Post authorisation request 2020***

Long term stability studies have been provided in post-authorization.

The product is considered stable after 30 months when stored in LDPE syringe, HDPE syringe, PP cartridge and PP syringe.

The product is considered stable after 24 months when stored in PS bait box and PET/PE + CRT/ALU/PE bait box.

The shelf life of 24 month as claimed in both packaging is thus confirmed with these post-authorization data.

***Conclusion of Efficacy***

FR CA assessed that the product DX3 Gel, has shown a sufficient efficacy for the following uses claimed:

Use as gel bait (drops) against garden ants (*Lasius niger*), argentine ants (*Linepithema humile*) and pharaoh ants (*Monomorium pharaonis*) at the application rate of 2 drops of 0.05 g each linear meter or per nest entrance, until 3 months after application, and for a shelf life of 3 years. The product control the population (with death of queen) and is effective within two weeks after application.

Use as bait box against garden ants (*Lasius niger*) at the application rate of 1 bait box every 15-20 m² or per nest entrance, until 3 months after opening, and for a shelf life of 3 years. The product control the population (with death of queen) and is effective within two weeks after application.

No specific crack and crevices test has been submitted because it was considered at the submission of this dossier (2018) that such application was cover by surface treatment.

Nevertheless, to take into account recent WG discussions, in case of an application for a change or at the renewal of authorisaton, to take into account recent WG discussions, new crack and crevices trials should be requested to confim the efficacy of the product DX3 GEL for this mode of application.

***Conclusion of risk characterisation for Human Health***

The risk for professional users is considered as acceptable without gloves. The risk for non-professional users, toddlers and infants is considered as acceptable.

The following RMM is proposed: “Apply the product safely in areas not accessible to children, pets and non-target animals”.

***Conclusion of risk for consumers via residues in food***

Considering the proposed PT18 biocidal use of the active substance imidacloprid as an ant gel bait, no risk for consumers via residues in food are expected. The following RMM is proposed: “Do not apply directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and animals.”

***Conclusion of risk characterisation for Environment:***

Considering the intended use of DX3 Gel, risks are acceptable whatever the way of environmental release in considering the specific conditions of use (indoor and outdoor). Nevertheless, the product contains the active substance imidacloprid known to be toxic to bees and therefore a risk for bees cannot be excluded.

For these reasons, FR CA suggests that when used outdoor, the product must be used in pre-filled bait boxes to protect from bees. When this is not practically possible, crack and crevice applications are also permitted in order to minimize access from non-target organisms. With respect to the condition of outdoor uses, honeybee exposure can be considered as negligible. The following RMM has been added by the FR CA:

* “For outdoor use, apply this biocidal product in bait boxes or in cracks and crevices only or directly to ant nests. Protect from bees and the weather by covering, for example with a flowerpot or a tile (ensuring that the ants still get access to the bait).”

***ED assessment:***

An assessment of endocrine disruption (ED) properties of co-formulants in the biocidal product DX3 Gel has been performed by FR CA. None of the co-formulants contained in the DX3 Gel product are identified as endocrine disruptors (cf. confidential Annex).

**GENERAL CONCLUSION:**

**FR CA considers that the product shall be authorized for**:

|  |  |  |
| --- | --- | --- |
| **Target organism** | **Application rates** | **Use conditions** |
| Black ant  *L. niger* (all stages of development);  Argentine ant  *L. humile* (all stages of development);  Pharaoh ant  *M. pharaonis* (all stages of development) | 2 drops of 0.05 g (5 mm of diameter) each linear meter or per nest entrance.  Population control (with death of queen) up to two weeks after application  Effective up to 3 months after application. Renew the application every 3 months or before if the bait is altered or totally consumed. | Professional users and general public  Indoors :indoors crack and crevices, along the walls  Outdoors: outdoors crack and crevices, outdoors around buildings, or in nest entrances.  For outdoor use, apply this biocidal product in cracks and crevices only or directly to ant nests. Protect from bees and the weather by covering, for example with a flowerpot or a tile (ensuring that the ants still get access to the bait). |
| Black ant  *L. niger* (all stages of development) | One bait box every 15 – 20 m2 or one bait box each nest entrance.  Population control (with death of queen) up to two weeks after application  Effective up to 3 months after opening | Professional users and general public  Indoors  Outdoors: outdoors around buildings, or near the nest. |

# ASSESSMENT REPORT

## Summary of the product assessment

### Administrative information

#### Identifier of the product

| **Identifier[[1]](#footnote-2)** | **Country (if relevant)** |
| --- | --- |
| DX3 GEL  SKULD ANT GEL  SKULD GEL BOX  KAMAZIL GEL  KAMAZIL ANT GEL  KAMAZIL GEL BOX  KAPTER ANT GEL  KAPTER ANT GEL BOX  KELT GEL  KELT ANT GEL  KELT GEL BOX  IMITEC GEL  IMITEC ANT GEL  IMITEC GEL BOX  DX3 ANT GEL  DX3 GEL BOX |  |

#### Authorisation holder

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | Zapi S.p.A. |
| **Address** | Via terza strada 12,  35026 Conselve (PD)  Padova  Italy |
| **Authorisation number** | **FR-2020-0014** | |
| **Date of the authorisation** | **09/03/2020** | |
| **Expiry date of the authorisation** | **08/03/2025** | |

#### Manufacturer(s) of the products

|  |  |
| --- | --- |
| **Name of manufacturer** | Zapi S.p.A. |
| **Address of manufacturer** | Via terza strada 12,  35026 Conselve (PD)  Padova  Italy |
| **Location of manufacturing sites** | Via terza strada 12,  35026 Conselve (PD)  Padova  Italy |

#### Manufacturer(s) of the active substance(s)

|  |  |
| --- | --- |
| **Active substance** | Imidacloprid |
| **Name of manufacturer** | Ningbo Generic Chemical Co., Ltd. (Art. 95 List: ZAPI S.p.A.) |
| **Address of manufacturer** | Room 10-6, Shidal Square 8, 315010, Zhejiang, China |
| **Location of manufacturing sites** | Shaanxi Hengtian Chemical Co., Ltd.,  Plant address: Dali Core Zone, Wei nan National Agricultural Science and Technology Park, Shanxi province, China |

### Product composition and formulation

NB: the full composition of the product according to Annex III Title 1 should be provided in the confidential annex.

Does the product have the same identity and composition as the product evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012?

Yes

No

#### Identity of the active substance

|  |  |
| --- | --- |
| **Main constituent(s)** | |
| **ISO name** | Imidacloprid (ISO) |
| **IUPAC or EC name** | (2E)-1-[(6-chloropyridin-3-yl) methyl]-N-nitroimidazolidin-2-imine |
| **EC number** | 428-040-8 |
| **CAS number** | 138261-41-3 |
| **Index number in Annex VI of CLP** | 612-252-00-4 |
| **Minimum purity / content** | 98% |
| **Structural formula** | http://www.alanwood.net/pesticides/structures/imidacloprid.gif |

#### Candidate(s) for substitution

The active substance imidacloprid contained in the biocidal products is a candidate for substitution in accordance with Article 10 of BPR, being very persistent (vP) and toxic (T) regarding environment.

#### Qualitative and quantitative information on the composition of the biocidal product[[2]](#footnote-3)

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |  |
| --- | --- | --- | --- | --- | --- | --- |
| Imidacloprid 98% (technical active substance) | (2E)-1-[(6-chloropyridin-3-yl) methyl]-N-nitroimidazolidin-2-imine | Active substance | 138261-41-3 | 428-040-8 | 0.0204 |  |
| *Pure active substance* | 0.020 |

#### Information on technical equivalence

According to the decision on technical equivalence under Art 54(4) of the BPR from the 1st of July 2016, the alternative source of Imidacloprid is considered technically equivalent compared to the reference source in respect of which the initial risk assessment was carried out.

#### Information on the substance(s) of concern

No substance of concern (SoC) has been identified.

Please see the confidential annex for further details.

#### Assessment of endocrine disruption (ED) properties of the biocidal product

According to our assessment, none of the co-formulants contained in the product DX3 GEL are regulatory identified as endocrine disruptors.

Please see the confidential annex for further details.

#### Type of formulation

|  |
| --- |
| RB, Gel Bait (ready for use) |

### Hazard and precautionary statements[[3]](#footnote-4)

**Classification and labelling of the products according to the Regulation (EC) 1272/2008**

*[It should also be stated if some P statements triggered by the criteria in CLP has been excluded due to the risk assessment.]*

| **Classification** | |
| --- | --- |
| Hazard category | Aquatic chronic 2 |
| Hazard statement | H411: Toxic to aquatic life with long lasting effects |
|  | |
| **Labelling** | |
| Signal words | - |
| Hazard statements | H411:Toxic to aquatic life with long lasting effects |
| Precautionary statements | P273: Avoid release to the environment  P391: Collect spillage  P501: Dispose of contents/container to accordance with local regulations. |
|  | |
| Note |  |

### Authorised use(s)

#### Use description

Table 1. Use # 1 – Gel bait application –Indoor and outdoor

|  |  |
| --- | --- |
| **Product Type** | PT18 - Insecticides, acaricides and products to control other arthropods (Pest control) |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Black ant  *L. niger* (all stages of development);  Argentine ant  *L. humile* (all stages of development);  Pharaoh ant  *M. pharaonis* (all stages of development)  Population control (with death of queen) up to two weeks after application. |
| **Field of use** | Indoors: indoors crack and crevices, along the walls  Outdoors: outdoors crack and crevices, outdoors around buildings, or in nest entrances. |
| **Application method(s)** | Bait application  Apply the product in drops along ants runways, or in crack and crevices, or in nest entrances, on horizontal non-absorbing surfaces. |
| **Application rate(s) and frequency** | Dose: 2 drops of 0.05 g (5 mm of diameter) each linear meter or per nest entrance.  Regularly verify the consumption of the product and replace it when it is exhausted.  Effective up to 3 months after application. Renew the application every 3 months or before if the bait is altered or totally consumed.  Time delay: two weeks after application |
| **Category(ies) of users** | Trained professional; Professional;  Non-professional |
| **Pack sizes and packaging material** | **For professional use:**  - HDPE syringes from 5 g up to 25 g (with increment of 1 g)  - Polypropylene syringes from 5 g up to 25 g (with increment of 1 g)  - LDPE syringes from 20 g up to 50 g (with increment of 1 g)  - Polypropylene cartridges from 25 g up to 50 g (with increment of 1 g)  The syringes or cartridges are packed in the following containers for placing on the market:  - Box (carton, or plastic, or a combination of carton and plastic) containing from 1 to 24 pieces (with increment of 1 piece)  - Blister (carton, or plastic, or a combination of carton and plastic) containing from 1 to 24 pieces (with increment of 1 piece)  - Carton box (carton) containing from 1 to 24 pieces (with increment of 1 piece)  - Bag (plastic or aluminum) containing from 1 to 24 pieces (with increment of 1 piece)  **For non-professional use:**  - HDPE syringes from 5 g up to 25 g (with increment of 1 g)  - Polypropylene syringes from 5 g up to 25 g (with increment of 1 g)  - LDPE syringes from 20 g up to 25 g (with increment of 1 g)  - Polypropylene cartridges of 25 g  The syringes or cartridges are packed in the following containers for placing on the market:  - Box (carton, or plastic, or a combination of carton and plastic) containing from 1 to 6 pieces (with increment of 1 piece)  - Blister (carton, or plastic, or a combination of carton and plastic) containing from 1 to 6 pieces (with increment of 1 piece)  - Carton box (carton) containing from 1 to 6 pieces (with increment of 1 piece)  - Bag (plastic or aluminum) containing from 1 to 6 pieces (with increment of 1 piece) |

#### Use-specific instructions for use

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| --- |
| * Do not apply the product on absorbing surfaces. * Do not expose bait drops to sunlight or heat (i.e radiator). * Maximum 30 drops of 0.05 g per nest (maximum 1.5 g of product). * Effective up to 3 months after application. Renew the application every 3 months or before if the bait is altered or totally consumed. |

#### Use-specific risk mitigation measures

|  |
| --- |
| * For outdoor use, apply this biocidal product in cracks and crevices only or directly to ant nests. Protect from bees and weather by covering, for example with a flowerpot or a tile (ensuring that the ants still get access to the bait). |

#### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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| - |

#### Where specific to the use, the instructions for safe disposal of the product and its packaging

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| - |

#### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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| - |

#### Use description

Table 2. Use # 2 – Non-professional and professional - Bait box application

|  |  |
| --- | --- |
| **Product Type** | PT18 - Insecticides, acaricides and products to control other arthropods (Pest control) |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Black ant  *L. niger* (all stages of development);  Population control (with death of queen) up to two weeks after application |
| **Field of use** | Indoors  Outdoors: outdoors around buildings, near the nest. |
| **Application method(s)** | In bait boxes (ready-to-use)  Apply the bait box where the presence of ants is noticed, i.e. along ants runways or near nest entrances, on horizontal surfaces according to the dosages indicated below. |
| **Application rate(s) and frequency** | Rate: one bait box every 15 – 20 m2 or one bait box each nest entrance.  Apply the bait box where the presence of ants is noticed.  If necessary, replace the bait box at the latest 3 months after its activation.  Effective up to 3 months after opening  Time delay: two weeks after application |
| **Category(ies) of users** | Trained professional;  Professional;  Non-professional |
| **Pack sizes and packaging material** | **For professional use:**  - Polystyrene bait box of 2 g, 3 g, 4 g  - Polypropylene bait box containing a 4 g capsule (PET/PE + CRT/ALU/PE)  - Polystyrene bait box containing a 4 g capsule (PET/PE + CRT/ALU/PE)  The bait boxes (each individually packed or not in single plastic or aluminum bags) are packed in the following containers for placing on the market:  - Box (carton, or plastic, or a combination of carton and plastic) containing from 1 to 24  pieces (with increment of 1 piece)  - Blister (carton, or plastic, or a combination of carton and plastic) containing from 1 to  24 pieces (with increment of 1 piece)  - Carton box (carton) containing from 1 to 24 pieces (with increment of 1 piece)  - Bag (plastic or aluminum) containing from 1 to 24 pieces (with increment of 1 piece)  **For non-professionals use :**  - Polystyrene bait box of 2 g, 3 g, 4 g  - Polypropylene bait box containing a 4 g capsule (PET/PE + CRT/ALU/PE)  - Polystyrene bait box containing a 4 g capsule (PET/PE + CRT/ALU/PE)  The bait boxes (each individually packed or not in single plastic or aluminum bags) are  packed in the following containers for placing on the market:  - Box (carton, or plastic, or a combination of carton and plastic) containing from 1 to  6 pieces (with increment of 1 piece)  - Blister (carton, or plastic, or a combination of carton and plastic) containing from 1 to  6 pieces (with increment of 1 piece)  - Carton box (carton) containing from 1 to 6 pieces (with increment of 1 piece)  - Bag (plastic or aluminum) containing from 1 to 6 pieces (with increment of 1 piece) |

#### Use-specific instructions for use[[4]](#footnote-5)

|  |
| --- |
| * If necessary, replace the bait box at the latest 3 months after its activation. |

#### Use-specific risk mitigation measures

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#### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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| - |

#### Where specific to the use, the instructions for safe disposal of the product and its packaging

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| - |

#### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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| - |

### General directions for use

#### Instructions for use

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| --- |
| * Always read the label or leaflet before use and respect all the instructions provided. * Avoid continuous use of the product. * Before treatment, remove all natural source of food for ants (waste, food scraps ...) from the infested area to encourage the ingestion of the gel. * Frequency to check the bait: once by week. * Remove the remaining bait or the bait containers at the end of the treatment period for following disposal. * Inform the registration holder if the treatment is ineffective. * For non-professionals only: If the infestation persists contact a professional. |

#### Risk mitigation measures

|  |
| --- |
| * Hazardous to bees. * Apply the product safely in areas not accessible to children, pets and non-target animals. * Do not apply directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and animals. |

#### Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| * Skin contact: Wash contaminated skin with soap and water. Contact poison treatment specialist if symptoms occur. * Eye contact: Immediately flush with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses if easy to do. Continue to rinse with tepid water for at least 10 minutes. Get medical attention if irritation or vision impairment occurs. * Mouth contact: Wash out mouth with water. Contact poison treatment specialist. * Keep the container or label available. |

#### Instructions for safe disposal of the product and its packaging

|  |
| --- |
| * Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets…) nor down the drains. * Dispose of unused product, its packaging and all other waste, in accordance with local regulations. |

#### Conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
| * Store in a cool and well-ventilated place away from heat sources. * Protect from light. * Protect from frost. * Shelf-life: 2 years. |

### Other information

|  |
| --- |
| * The product contains a bittering agent. |

### Packaging of the biocidal product

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Type of packaging** | **Size/volume of the packaging** | **Material of the packaging** | **Type and material of closure(s)** | | **Intended user (e.g. professional, non-professional)** | **Compatibility of the product with the proposed packaging materials (Yes/No)** |
| Syringe | from 5 g up to 25 g (with increment of 1 g) | HDPE | | LDPE | non-professional | yes |
| Syringe | from 5 g up to 25 g (with increment of 1 g) | Polypropylene | | Polypropylene | non-professional | yes |
| Syringe | from 20 g up to 25 g (with increment of 1 g) | LDPE | | PE | non-professional | yes |
| Cartridge | 25 g | Polypropylene | | Polypropylene | non-professional | yes |
| Bait box | 2 g, 3 g, 4 g | Polystyrene | | Polystyrene | non-professional | yes |
| Bait box (PP or PS) containing a 4 g capsule | 4 g | PET/PE + CRT/ALU/PE | | PET/PE + CRT/ALU/PE | non-professional | yes |
| Syringe | from 5 g up to 25 g (with increment of 1 g) | HDPE | | LDPE | Professional, Trained professional | yes |
| Syringe | from 5 g up to 25 g (with increment of 1 g) | Polypropylene | | Polypropylene | Professional, Trained professional | yes |
| Syringe | from 20 g up to 50 g (with increment of 1 g) | LDPE | | PE | Professional, Trained professional | yes |
| Cartridge | from 25 g up to 50 g (with increment of 1 g) | Polypropylene | | Polypropylene | Professional, Trained professional | yes |
| Bait box | 2 g, 3 g, 4 g | Polystyrene | | Polystyrene | Professional, Trained professional | yes |
| Bait box (PP or PS) containing a 4 g capsule | 4 g | PET/PE + CRT/ALU/PE | | PET/PE + CRT/ALU/PE | Professional, Trained professional | yes |

### Documentation

#### Data submitted in relation to product application

Physico-chemical properties studies and analytical methods on the biocidal product DX3GEL were provided by Zapi Industry.

*-* **Efficacy data (see ANNEX 3.5 Summaries of the efficacy studies).**

The following efficacy studies were submitted:

**Gel bait in syringes:**

* A semi-field study (vivarium) according to CEB N°196 method[[5]](#footnote-6) conducted with the product DX3 GEL (0.02% w/w Imidacloprid), fresh formulation on one ant species black garden ant (*Lasius niger*).
* A semi-field study (vivarium) according to CEB N°196 method conducted with the product DX3 GEL (0.02% w/w Imidacloprid), opened 3 months before test, on one ant species black garden ant (*Lasius niger*).
* A semi-field study (vivarium) according to CEB N°196 method conducted with the product DX3 GEL (0.02% w/w Imidacloprid), 3 years aged formulation on one ant species black garden ant (*Lasius niger*).
* A field test conducted with the product DX3 GEL (0.02% w/w Imidacloprid), fresh formulation on one ant species black garden ant (*Lasius niger*).
* A semi-field study (vivarium) according to CEB N°196 method conducted with the product DX3 GEL (0.02% w/w Imidacloprid), fresh formulation on one ant species argentine ant (*Linepithema humile*).
* A semi-field study (vivarium) according to CEB N°196 method conducted with the product DX3 GEL (0.02% w/w Imidacloprid), opened 3 months before test, on one ant species argentine ant (*Linepithema humile*).
* A semi-field study (vivarium) according to CEB N°196 method conducted with the product DX3 GEL (0.02% w/w Imidacloprid), 3 years aged formulation on one ant species argentine ant (*Linepithema humile*).
* A field test conducted with the product DX3 GEL (0.02% w/w Imidacloprid), fresh formulation on one ant species argentine ant (*Linepithema humile*).
* A semi-field study (vivarium) according to CEB N°196 method conducted with the product DX3 GEL (0.02% w/w Imidacloprid), fresh formulation on one ant species pharaoh ant (*Monomorium pharaonis*).
* A semi-field study (vivarium) according to CEB N°196 method conducted with the product DX3 GEL (0.02% w/w Imidacloprid), opened 3 months before test, on one ant species pharaoh ant (*Monomorium pharaonis*).
* A semi-field study (vivarium) according to CEB N°196 method conducted with the product DX3 GEL (0.02% w/w Imidacloprid), 3 years aged formulation on one ant species pharaoh ant (*Monomorium pharaonis*).
* A field test conducted with the product DX3 GEL (0.02% w/w Imidacloprid), fresh formulation on one ant species pharaoh ant (*Monomorium pharaonis*).

**Gel bait in box:**

* A semi-field study (vivarium) according to CEB N°196 method conducted with the product DX3 GEL (bait box) (0.02% w/w Imidacloprid), fresh formulation on one ant species black garden ant (*Lasius niger*).
* A semi-field study (vivarium) according to CEB N°196 method conducted with the product DX3 GEL (bait box) (0.02% w/w Imidacloprid), opened 3 months before test, on one ant species black garden ant (*Lasius niger*).
* A semi-field study (vivarium) according to CEB N°196 method conducted with the product DX3 GEL (bait box) (0.02% w/w Imidacloprid), 3 years aged formulation on one ant species black garden ant (*Lasius niger*).
* A field test conducted with the product DX3 GEL (bait box) (0.02% w/w Imidacloprid), fresh formulation on one ant species black garden ant (*Lasius niger*).

#### Access to documentation

Applicant is the data holder.

## Assessment of the biocidal product

### Intended use(s) as applied for by the applicant

Use # 1 – Non professional and professional – bait application

|  |  |
| --- | --- |
| **Product Type** | PT18 - Insecticides, acaricides and products to control other arthropods (Pest control) |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | *L. niger* (all stages of development);  *L. humile* (all stages of development);  *M. pharaonis* (all stages of development) |
| **Field of use** | Indoors, indoors crack and crevices, outdoors, outdoors crack and crevices, outdoors around buildings, and on nest. |
| **Application method(s)** | Bait application |
| **Application rate(s) and frequency** | Apply the product in drops along ants runways, or in crack and crevices, or near nest entrances, on horizontal non-absorbing surfaces. A drop of 0.05 g has a diameter of about 5 mm.  Ants: 2 drops of 0.05 g each linear meter  Ants nest: maximum 30 drops of 0.05 g per nest (maximum 1.5 g of product).  Regularly verify the consumption of the product and replace it when it is exhausted. |
| **Category(ies) of users** | Trained professional; Professional; Non - professional (general public) |
| **Pack sizes and packaging material** | **For non-professional use:**  The product is supplied as:  - syringes (HDPE, or PP) from 5 g up to 25 g (with increment of 1 g)  - syringes (LDPE) from 20 g up to 25 g (with increment of 1 g)  - cartridges (PP) of 25 g  The syringes or cartridges are packed in the following containers for placing on the market:   * Box (carton, or plastic, or a combination of carton and plastic) containing from 1 to 6 pieces (with increment of 1 piece) * Blister (carton, or plastic, or a combination of carton and plastic) containing from 1 to 6 pieces (with increment of 1 piece) * Carton box (carton) containing from 1 to 6 pieces (with increment of 1 piece) * Bag (plastic or aluminum) containing from 1 to 6 pieces (with increment of 1 piece)   **For professional use:**  The product is supplied as:  - syringes (HDPE, or PP) from 5 g up to 25 g (with increment of 1 g)  - syringes (LDPE) from 20 g up to 50 g (with increment of 1 g)  - cartridges (PP) from 25 g up to 50 g (with increment of 1 g)  The syringes or cartridges are packed in the following containers for placing on the market:  Box (carton, or plastic, or a combination of carton and plastic) containing from 1 to 24 pieces (with increment of 1 piece)  Blister (carton, or plastic, or a combination of carton and plastic) containing from 1 to 24 pieces (with increment of 1 piece)  Carton box (carton) containing from 1 to 24 pieces (with increment of 1 piece)  Bag (plastic or aluminum) containing from 1 to 24 pieces (with increment of 1 piece) |

Use # 2 – Non-professional and professional - Bait box application

|  |  |
| --- | --- |
| **Product Type** | PT18 - Insecticides, acaricides and products to control other arthropods (Pest control) |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | *L. niger* (all stages of development) |
| **Field of use** | Indoors, indoors crack and crevices, outdoors, outdoors crack and crevices, outdoors around buildings, and on nest. |
| **Application method(s)** | In bait boxes |
| **Application rate(s) and frequency** | Apply the bait box where the presence of ants is noticed, i.e. along ants runways or near nest entrances, on horizontal surfaces according to the dosages indicated below.  Rate: one bait box every 15 – 20 m2 or one bait box each nest entrance.  Apply the bait box where the presence of ants is noticed.  If necessary, replace the bait box at the latest 3 months after its activation. |
| **Category(ies) of users** | Trained professional; Professional; Non - professional (general public) |
| **Pack sizes and packaging material** | **For non-professional use:**  The product is supplied as:  - bait box (PS) of 2 g, 3 g, 4 g  - bait box (PP or PS) containing a 4 g capsule (PET/PE + CRT/ALU/PE)  The bait boxes (each individually packed or not in single plastic or aluminum bags) are packed in the following containers for placing on the market:  - Box (carton, or plastic, or a combination of carton and plastic) containing from 1 to 6 pieces (with increment of 1 piece)  - Blister (carton, or plastic, or a combination of carton and plastic) containing from 1 to 6 pieces (with increment of 1 piece)  - Carton box (carton) containing from 1 to 6 pieces (with increment of 1 piece)  - Bag (plastic or aluminum) containing from 1 to 6 pieces (with increment of 1 piece)  **For professional use:**  The product is supplied as:  - bait box (PS) of 2 g, 3 g, 4 g  - bait box (PP or PS) containing a 4 g capsule (PET/PE + CRT/ALU/PE)  The bait boxes (each individually packed or not in single plastic or aluminum bags) are packed in the following containers for placing on the market:  - B﻿ox (carton, or plastic, or a combination of carton and plastic) containing from 1 to 24 pieces (with increment of 1 piece)  - Blister (carton, or plastic, or a combination of carton and plastic) containing from 1 to 24 pieces (with increment of 1 piece)  - Carton box (carton) containing from 1 to 24 pieces (with increment of 1 piece)  - Bag (plastic or aluminum) containing from 1 to 24 pieces (with increment of 1 piece) |

### Physical, chemical and technical properties

The notifier Zapi is listed as substance supplier for the active substance Imidacloprid according to Article 95 of regulation (EU) No 528/2012.

The biocidal product is not the same than the one assessed for the inclusion of the active substances in annex 1 of directive 98/8/EC. The composition of the product is confidential and is presented in a confidential annex. The product contains 0.02% of technical active substance (purity 98%).

The product does not contain PT6 preservative.

Formulation type: RB Bait (ready for use)

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** | **FR evaluation** |
| --- | --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | OPPTS 830.6302 | Content Imidacloprid: 0.02% | Gel  No data is available to determine if the biocidal product should be defined as a solid or a liquid according to CLP. Based on the composition of the product, no classification for physical hazard is expected whether the product is considered as a liquid or a solid, no more data required. | Urbani M. 2017, CH 585/2017 | Acceptable |
| Colour at 20 °C and 101.3 kPa | OPPTS 830.6303 | Content Imidacloprid: 0.02% | Colourless | Urbani M. 2017, CH 585/2017 | Acceptable |
| Odour at 20 °C and 101.3 kPa | OPPTS 830.6304 | Content Imidacloprid: 0.02% | Characteristic odour | Urbani M. 2017, CH 585/2017 | Acceptable |
| Acidity / alkalinity | CIPAC MT 75.3 and OECD No. 122 (2013) | Content Imidacloprid: 0.02% | From the experimental data obtained according to CIPAC method MT 75.3, it can be concluded that the pH value of a 1 % w/v aqueous dispersion of the DX3 gel bait formulation sample is 6.9 (rounded mean value of two measurements). | Urbani M. 2017, CH 585/2017 | Acceptable |
| Relative density / bulk density | CIPAC MT 3.2, OECD No. 109 and EC Regulation No. 440/2008 A.3 | Content Imidacloprid: 0.02% | the density of the DX3 gel bait formulation sample is 1.3503 g/mL at 20°C; the specific gravity is 1.3527 at 20°C, and the relative density is 1.3503. | Urbani M. 2017, CH 585/2017 | Acceptable |
| Storage stability test – **accelerated storage** | OPPTS 830.6302, OPPTS 830.6303, OPPTS 830.6304,  CIPAC MT 75.3 and OECD No. 122 (2013),  CIPAC MT 3.2, OECD No. 109 and EC Regulation No. 440/2008 A.3,  CIPAC MT 192 and OECD No. 114,  Internal Analytical Method No. 586/2017 | Content Imidacloprid: 0.02%,  Packed in:  LDPE, HDPE, PP, PS, PET/PE +CRT/ALU/PE | **20g LDPE syringe:**      **5g HDPE syringe:**    **25g PP cartridge:**    **5g PP syringe:**      **2g PS bait box:**    **4g PET/PE+CRT/ALU/PE bait box:**  (\*) Since the pH value ranged from 4 to 10, the acidity or alkalinity test was not performed.  From the above reported data, it can be concluded that the sample of DX3 gel bait formulation is stable in all its commercial packagings under the tested accelerated storage conditions. | Urbani M. 2017,  CH 587/2017;  CH 588/2017;  CH 589/2017;  CH 678/2017;  CH 042/2018;  CH 045/2018; | Acceptable  The preparation is stable in its commercial packaging after 14 days at 54°C when stored in LDPE syringes, HDPE syringes, PP cartridges and bait boxes.  The preparation is stable in its commercial packaging after 12 weeks at 35°C when stored in PP syringes. |
| Storage stability test – **long term storage at ambient temperature** | OPPTS 830.6302, OPPTS 830.6303, OPPTS 830.6304,  CIPAC MT 75.3 and OECD No. 122 (2013),  CIPAC MT 3.2, OECD No. 109 and EC Regulation No. 440/2008 A.3,  CIPAC MT 192 and OECD No. 114,  Internal Analytical Method No. 586/2017 | Content Imidacloprid: 0.02%,  Packed in:  LDPE, HDPE, PP, PS, PET/PE +CRT/ALU/PE | **20 g LDPE syringe:**   |  |  |  | | --- | --- | --- | | **Test** | **Initial characterisation** | **After 12 months** | | Weight variation (%) | -0.03% | | | Compatibility of the packaging material | The container didn’t present any deformation in both bottom and lateral layers, or loss of sample and evident corrosion phenomena and the syringe worked properly | | | Imidacloprid active ingredient content | 0.021 % w/w | 0.022 % w/w | | Appearance | Colourless gel  With characteristic odour | Colourless gel  With characteristic odour | | Ph value | 6.9 | 6.9 | | Relative density | 1.3503 g/ml at 20°c | 1.3355 g/ml at 20°c | | Viscosity | Dynamic viscosity:  From 10060.0 cp  To 8536.7 cp at 20°c  From 2330.0 cp  To 1946.0 cp at 40°c | Dynamic viscosity:  From 8960.0 cp  To 7523.3 cp at 20°c  From 1863.3 cp  To 1538.0 cp at 40°c |  |  |  |  | | --- | --- | --- | | **Test** | **After 24 months** | **After 30 months** | | Weight variation (%) | -0.10% | -0.15% | | Compatibility of the packaging material | The container didn’t present any deformation in both bottom and lateral layers, or loss of sample and evident corrosion phenomena and the syringe worked properly | | | Imidacloprid active ingredient content | 0.021 % w/w | 0.020 % w/w | | Appearance | Colourless gel  With characteristic odour | Colourless gel  With characteristic odour | | Ph value | 7 | 7.2 | | Relative density | 1.3246 g/ml at 20°c | 1.3232 g/ml at 20°c | | Viscosity | Dynamic viscosity:  From 9723 cp  To 8313 cp at 20°c  From 2003 cp  To 1795 cp at 40°c | Dynamic viscosity:  From 9716 cp  To 8286 cp at 20°c  From 2016 cp  To 1795 cp at 40°c |   **5 g HDPE syringe:**   |  |  |  | | --- | --- | --- | | **Test** | **Initial characterisation** | **After 12 months** | | Weight variation (%) | -0.06% | | | Compatibility of the packaging material | The container didn’t present any deformation in both bottom and lateral layers, or loss of sample and evident corrosion phenomena and the syringe worked properly | | | Imidacloprid active ingredient content | 0.021 % w/w | 0.022 % w/w | | Appearance | Colourless gel  With characteristic odour | Colourless gel  With characteristic odour | | Ph value | 6.9 | 6.9 | | Relative density | 1.3503 g/ml at 20°c | 1.3392 g/ml at 20°c | | Viscosity | Dynamic viscosity:  From 10060.0 cp  To 8536.7 cp at 20°c  From 2330.0 cp  To 1946.0 cp at 40°c | Dynamic viscosity:  From 9013.3 cp  To 7933.3 cp at 20°c  From 1823.3 cp  To 1490.0 cp at 40°c |  |  |  |  | | --- | --- | --- | | **Test** | **After 24 months** | **After 30 months** | | Weight variation (%) | -0.2% | -0.1% | | Compatibility of the packaging material | The container didn’t present any deformation in both bottom and lateral layers, or loss of sample and evident corrosion phenomena and the syringe worked properly | | | Imidacloprid active ingredient content | 0.022 % w/w | 0.020 % w/w | | Appearance | Colourless gel  With characteristic odour | Colourless gel  With characteristic odour | | Ph value | 6.9 | 6.9 | | Relative density | 1.3391 g/ml at 20°c | 1.3390 g/ml at 20°c | | Viscosity | Dynamic viscosity:  From 9033 cp  To 7970 cp at 20°c  From 1843 cp  To 1496 cp at 40°c | Dynamic viscosity:  From 9023 cp  To 7980 cp at 20°c  From 1830 cp  To 1500 cp at 40°c |   **25 g PP cartridge:**   |  |  |  | | --- | --- | --- | | **Test** | **Initial characterisation** | **After 12 months** | | Weight variation (%) | -0.03% | | | Compatibility of the packaging material | The container didn’t present any deformation in both bottom and lateral layers, or loss of sample and evident corrosion phenomena and the cartridge worked properly | | | Imidacloprid active ingredient content | 0.021 % w/w | 0.021 % w/w | | Appearance | Colourless gel  With characteristic odour | Colourless gel  With characteristic odour | | Ph value | 6.9 | 6.9 | | Relative density | 1.3503 g/ml at 20°c | 1.3429 g/ml at 20°c | | Viscosity | Dynamic viscosity:  From 10060.0 cp  To 8536.7 cp at 20°c  From 2330.0 cp  To 1946.0 cp at 40°c | Dynamic viscosity:  From 9423.3 cp  To 8180.0 cp at 20°c  From 1756.7 cp  To 1506.7 cp at 40°c |  |  |  |  | | --- | --- | --- | | **Test** | **After 24 months** | **After 30 months** | | Weight variation (%) | -0.14% | -0.11% | | Compatibility of the packaging material | The container didn’t present any deformation in both bottom and lateral layers, or loss of sample and evident corrosion phenomena and the cartridge worked properly | | | Imidacloprid active ingredient content | 0.022 % w/w | 0.021 % w/w | | Appearance | Colourless gel  With characteristic odour | Colourless gel  With characteristic odour | | Ph value | 6.9 | 6.8 | | Relative density | 1.3426 g/ml at 20°c | 1.3429 g/ml at 20°c | | Viscosity | Dynamic viscosity:  From 9383 cp  To 8150 cp at 20°c  From 1780 cp  To 1520 cp at 40°c | Dynamic viscosity:  From 9400 cp  To 8120 cp at 20°c  From 1783 cp  To 1476 cp at 40°c |   **5 g PP syringe:**   |  |  |  | | --- | --- | --- | | **Test** | **Initial characterisation** | **After 12 months** | | Weight variation (%) | -0.05% | | | Compatibility of the packaging material | The container didn’t present any deformation in both bottom and lateral layers, or loss of sample and evident corrosion phenomena and the syringe worked properly | | | Imidacloprid active ingredient content | 0.021 % w/w | - | | Appearance | Colourless gel  With characteristic odour | - | | Ph value | 6.9 | - | | Relative density | 1.3503 g/ml at 20°c | - | | Viscosity | Dynamic viscosity:  From 10060.0 cp  To 8536.7 cp at 20°c  From 2330.0 cp  To 1946.0 cp at 40°c | - |  |  |  |  | | --- | --- | --- | | **Test** | **After 24 months** | **After 30 months** | | Weight variation (%) | -0.12% | -0.35% | | Compatibility of the packaging material | The container didn’t present any deformation in both bottom and lateral layers, or loss of sample and evident corrosion phenomena and the syringe worked properly | | | Imidacloprid active ingredient content | - | - | | Appearance | - | - | | Ph value | - | - | | Relative density | - | - | | Viscosity | - | - |   **2 g PS bait box:**   |  |  |  | | --- | --- | --- | | **Test** | **Initial characterisation** | **After 6 months** | | Weight variation (%) | +1.72% | | | Compatibility of the packaging material | The container didn’t present any deformation in both bottom and lateral layers, or loss of sample and evident corrosion phenomena. | | | Imidacloprid active ingredient content | 0.021 % w/w | 0.020 % w/w | | Appearance | Colourless gel  with characteristic odour | - | | pH value | 6.9 | - | | Relative density | 1.3503 g/mL at 20°C | - | | Viscosity | Dynamic viscosity:  from 10060.0 cP  to 8536.7 cP at 20°C  from 2330.0 cP  to 1946.0 cP at 40°C | - |  |  |  |  | | --- | --- | --- | | **Test** | **After 18 months** | **After 24 months** | | Weight variation (%) | 2.18% | 2.19% | | Compatibility of the packaging material | The container didn’t present any deformation in both bottom and lateral layers, or loss of sample and evident corrosion phenomena; | | | Imidacloprid active ingredient content | 0.020 % w/w | 0.020 % w/w | | Appearance | - | Colourless gel  With characteristic odour | | Ph value | - | 6.9 | | Relative density | - | 1.2521 g/ml at 20°c | | Viscosity | - | Dynamic viscosity:  From 4453 cp  To 3170 cp at 20°c  From 993 cp  To 726 cp at 40°c |   **4 g PET/PE + CRT/ALU/PE bait box:**   |  |  |  | | --- | --- | --- | | **Test** | **Initial characterisation** | **After 6 months** | | Weight variation (%) | -1.43% | | | Compatibility of the packaging material | The container didn’t present any deformation in both bottom and lateral layers, or loss of sample and evident corrosion phenomena. | | | Imidacloprid active ingredient content | 0.022 % w/w | 0.022 % w/w | | Appearance | Colourless gel  With characteristic odour | - | | Ph value | 6.9 | - | | Relative density | 1.3503 g/ml at 20°c | - | | Viscosity | Dynamic viscosity:  From 10060.0 cp  To 8536.7 cp at 20°c  From 2330.0 cp  To 1946.0 cp at 40°c | - |  |  |  |  | | --- | --- | --- | | **Test** | **After 18 months** | **After 24 months** | | Weight variation (%) | -4.29% | -5.18% | | Compatibility of the packaging material | The container didn’t present any deformation in both bottom and lateral layers, or loss of sample and evident corrosion phenomena. | | | Imidacloprid active ingredient content | 0.021 % w/w | 0.020 % w/w | | Appearance | - | Colourless gel  With characteristic odour | | Ph value | - | 6.8 | | Relative density | - | 1.3465 g/ml at 20°c | | Viscosity | - | Dynamic viscosity:  From 13133 cp  To 11886 cp at 20°c  From 2506 cp  To 2136 cp at 40°c | | Study CH-592/2017  Study CH-593/2017  Study CH-594/2017  Study CH-044/2018  Study CH-046/2018  Simona Nichetti | Acceptable  **Post authorisation 2020:**  The product is considered stable after 30 months when stored in LDPE syringe, HDPE syringe, PP cartridge and PP syringe.  The product is considered stable after 24 months when stored in PS bait box and PET/PE + CRT/ALU/PE bait box. |
| Storage stability test – **low temperature stability test for liquids** | / | / | No low temperature studies were performed. | / | **The product must be protected from frost.** |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | / | / | Not applicable. label claim "protect and store the product away from light". | / | Acceptable  **The product must be protected from light.** |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | / | / | Not applicable because according to the label instructions the biocidal product has to be stored tightly closed in a cool place. | / | Acceptable |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | Accelerated storage | Content Imidacloprid: 0.02%,  Packed in:  LDPE, HDPE, PP, PS, PET/PE +CRT/ALU/PE | The sample of DX3 gel bait formulation is stable in its commercial packaging under the tested accelerated storage conditions. | Urbani M. 2017,  CH 587/2017;  CH 588/2017;  CH 589/2017;  CH 678/2017;  CH 042/2018;  CH 045/2018 | Data are present to demonstrate stability in HDPE. As biocidal product is a water solution, read across to PP is considered acceptable.  Acceptable |
| Wettability | / | / | Since the biocidal product is a gel formulation not intended to be dispersed in water this test does not need to be performed. | / | Acceptable |
| Suspensibility, spontaneity and dispersion stability | / | / | Since the biocidal product is a ready-to-use gel formulation these tests do not need to be performed. | / | Acceptable |
| Wet sieve analysis and dry sieve test | / | / | Since the biocidal product is a gel, no dispersable concentrate and no suspension, these tests do not need to be performed. | / | Acceptable |
| Emulsifiability, re-emulsifiability and emulsion stability | / | / | Since the biocidal product is a ready-to-use product these tests do not need to be performed. | / | Acceptable |
| Disintegration time | / | / | Since the biocidal product is a gel formulation this test does not need to be performed. | / | Acceptable |
| Particle size distribution, content of dust/fines, attrition, friability | / | / | Since the biocidal product is a gel formulation this test does not need to be performed. | / | Acceptable |
| Persistent foaming | / | / | Since the biocidal product is not intended for dilution with water before use, this test does not need to be performed. | / | Acceptable |
| Flowability/Pourability/Dustability | / | / | Since no equipment is needed for the application of the biocidal product and since the biocidal product is no suspension, emulsion, or dust these tests do not need to be performed. | / | Acceptable |
| Burning rate — smoke generators | / | / | Since the biocidal product is not a smoke generator this test does not need to be performed. | / | Acceptable |
| Burning completeness — smoke generators | / | / | Since the biocidal product is not a smoke generator this test does not need to be performed. | / | Acceptable |
| Composition of smoke — smoke generators | / | / | Since the biocidal product is not a smoke generator this test does not need to be performed. | / | Acceptable |
| Spraying pattern — aerosols | / | / | Since the biocidal product is not an aerosol this test does not need to be performed. | / | Acceptable |
| Physical compatibility | / | / | The product is not applied in mixture with other products. For this reason, a derogation to perform these studies is requested. | / | Acceptable |
| Chemical compatibility | / | / | The product is not applied in mixture with other products. For this reason, a derogation to perform these studies is requested. | / | Acceptable |
| Degree of dissolution and dilution stability | / | / | Since the biocidal product is not a water soluble bag, tablet or a water-soluble preparation these tests do not need to be performed. | / | Acceptable |
| Surface tension | / | / | Since the biocidal product is a gel formulation aspiration of it can be excluded. Therefore the surface tension of the formulation does not need to be tested. | / | Acceptable |
| Viscosity | CIPAC MT 192 and OECD No. 114 | Content Imidacloprid: 0.02% | The test item is a non-Newtonian liquid and its dynamic viscosity changes with the shear rate.  The dynamic viscosity ranges of the DX3 gel bait formulation sample, determined at 20°C and 40°C, using a cylindrical spindle, are as follows:  Dynamic viscosity (20°C): from 10060.0 cP to 8536.7 cP  (from 10060.0 mPa\*s to 8536.7 mPa\*s)  Dynamic viscosity (40°C): from 2330.0 cP to 1946.0 cP  (from 2330.0 mPa\*s to 1946.0 mPa\*s) | Urbani M. 2017, CH 585/2017 | Acceptable |

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| **Conclusion on the physical, chemical and technical properties of the product** |
| The product DX3GEL is a ready for use bait (RB) formulation. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable.  The appearance of the product is a colourless gel with a characteristic odour. There is no effect of high temperature on the stability of the formulation, since after 14 days at 54°C, neither the active ingredient content nor the technical properties were changed when stored in LDPE syringes, HDPE syringes, PP cartridges and bait boxes. After 12 weeks at 35°C, neither the active ingredient content nor the technical properties were changed when stored in PP syringes. The accelerated storage of the product indicates that the biocidal product is expected to be stable 2 years at ambient temperature. However, a long term storage stability study (on-going) is needed to prove the stability of the product in post-authorization.  The product should be protected from light and frost.  **Post authorisation 2020:**  The product is considered stable after 30 months when stored in LDPE syringe, HDPE syringe, PP cartridge and PP syringe.  The product is considered stable after 24 months when stored in PS bait box and PET/PE + CRT/ALU/PE bait box.  The shelf life of 24 month in both packaging is thus confirmed with these post-authorization data.  Its technical characteristics are acceptable for an RB formulation. |

### Physical hazards and respective characteristics

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **FR evaluation** | **Reference** |
| --- | --- | --- | --- | --- | --- |
| Explosives | Statement | - | The study does not need to be conducted because there are no chemical groups in the molecule which are associated with explosive properties. | Acceptable | See IUCLID section 4.1 |
| Flammable gases |  | - | None of the components are classified under 67/548/EEC, 1272/2008/EC and/or 1999/45/EC norms. | Not relevant as the product is not a gaz | - |
| Flammable aerosols |  | - | None of the components are classified under 67/548/EEC, 1272/2008/EC and/or 1999/45/EC norms. | Not relevant as the product is not an aerosol*.* | - |
| Oxidising gases |  | - | None of the components are classified under 67/548/EEC, 1272/2008/EC and/or 1999/45/EC norms. | Not relevant as the product is not a gaz | - |
| Gases under pressure |  | - | None of the components are classified under 67/548/EEC, 1272/2008/EC and/or 1999/45/EC norms. | Not relevant as the product is not a gas under pressure | - |
| Flammable liquids | EC Regulation No. 440/2008 A.9 | 98% | The DX3 gel bait formulation sample present no flash point until 130°C (maximum temperature apparatus) and it is not flammable. | Acceptable  The preparation is not flammable. | Urbani M. 2017, CH-585/2017 |
| Flammable solids | - | - | - | Not relevant as the flammable liquid property was tested | - |
| Self-reactive substances and mixtures |  | - | None of the components are classified under 67/548/EEC, 1272/2008/EC and/or 1999/45/EC norms.  The study does not need to be conducted because there are no chemical groups present in the molecule which are associated with explosive or self-reactive properties | No test is available in the dossier. However, no self heating property is expected due to the simple composition of the product (sorbitol/water/sucrose)  Furthermore, imidacloprid is not known to have self heating properties | See IUCLID section 4.8 |
| Pyrophoric liquids |  | - | None of the components are classified under 67/548/EEC, 1272/2008/EC and/or 1999/45/EC norms. | Acceptable | - |
| Pyrophoric solids |  | - | None of the components are classified under 67/548/EEC, 1272/2008/EC and/or 1999/45/EC norms. | Acceptable | - |
| Self-heating substances and mixtures |  | - | None of the components are classified under 67/548/EEC, 1272/2008/EC and/or 1999/45/EC norms. | BP is a water based product. | - |
| Substances and mixtures which in contact with water emit flammable gases |  | - | None of the components are classified under 67/548/EEC, 1272/2008/EC and/or 1999/45/EC norms. | Acceptable | - |
| Oxidising liquids | Statement | - | The study does not need to be conducted because there are no chemical groups present in the molecule which are associated with oxidizing properties and hence, the classification procedure does not need to be applied. | Acceptable | - |
| Oxidising solids | Statement | - | The study does not need to be conducted because there are no chemical groups present in the molecule which are associated with oxidizing properties and hence, the classification procedure does not need to be applied. | Acceptable | IUCLID |
| Organic peroxides |  | - | None of the components are classified under 67/548/EEC, 1272/2008/EC and/or 1999/45/EC norms.  The study does not need to be conducted because the substance does not fall under the definition of organic peroxides according to GHS and the relevant UN Manual of tests and criteria | Acceptable | See IUCLID 4.15 |
| Corrosive to metals |  | - | None of the components are classified under 67/548/EEC, 1272/2008/EC and/or 1999/45/EC norms.  The product does not have an extreme pH value nor contain any component able to corrode metals. | Halogen is present in the active substance but the halogen is not labile. In addition, imidacloprid is not classified as corrosive to metal.  eCA considers that is is unlikely that the biocidal product is corrosive to metal. | - |
| Auto-ignition temperatures of products (liquids and gases) | Statement | - | the product was demonstrated to be not flammable up to 130°C.  Autoignition point > 130°C | Acceptable | - |
| Relative self-ignition temperature for solids |  | - | None of the components are classified under 67/548/EEC, 1272/2008/EC and/or 1999/45/EC norms. | No self heating property is expected due to the simple composition of the product.  Furthermore, imidacloprid is not known to have self heating properties (melting point 140°C, no decomposition below 200°C) | - |
| Dust explosion hazard |  | - | None of the components are classified under 67/548/EEC, 1272/2008/EC and/or 1999/45/EC norms. | Acceptable | - |

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| **Conclusion on the physical hazards and respective characteristics of the product** |
| The product is not flammable. It has no explosive and no oxidizing properties.  The product is not classified with regard to physical and chemical properties.  A full CLP data package will be required for renewal of the product. This is particulary relevant for self reactive and corrosion to metal properties. |

### Methods for detection and identification

**Analytical method for the determination of the active substance in the biocidal product**

Report: DX3 gel bait: Validation of the Analytical Method for the determination of the Active Ingredient Content, M. Urbani, 2017

Report no CH-586/2017

Test facility: ChemService S.r.l. Controlli e Ricerche

GLP Studies Department

Via F.lli Beltrami, 15

20026 Novate Milanese - MI - (Italy)

Principle of the method:

The determination of Imidacloprid is performed by HPLC, using an internal standard and UV detector.

The validation of this method was considered in compliance with SANCO/3030/99 rev.4.

Validation data:

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| --- | --- | --- |
| Specificity | To demonstrate the specificity of the method, several solution are analyzed:   * Solvent blank (methanol) * Ethyl paraben internal standard * Imidacloprid reference material * Placebo * Test item of the product   No interference was found: no peak appears in the solvent blank, one peak is observed at the same retention time for the reference item and test item.  All chromatograms were available.  The analytical method was shown to be specific for Imidacloprid active ingredient in the DX3 gel bait formulation samples | |
| Linearity | Linearity was studied by carrying out five concentrations between ±40% of the solution concentration used for the quantification analysis.  Calibration curve has been provided with a r2 higher than 0.99. | |
| Compound | Linearity % |
| Imidacloprid | 30.33 to 70.77 µg/mL  Y = 801669X – 1373061 R2 = 0.99892  n=5 |
| Precision | Repeatability was evaluated by analyzing five test item solutions. | |
| Compound | Repeatability (RSD) |
| Imidacloprid (0.021% w/w) | RSD = 1.59%  Horwitz RSDr = 4.79 % |
| Accuracy | Accuracy was determined at 3 levels in duplicate, corresponding to additions of 75%, 100% and 125% of the nominal concentration of active ingredient. The accuracy results are expressed as the recovery rate.   |  |  |  |  | | --- | --- | --- | --- | | Fortification level | Recovery rate (%) | Mean recovery rate (%) | n | | 75% | 102.21, 102.15 | 102.2 | 2 | | 100% | 101.47, 101.38 | 101.4 | 2 | | 125% | 98.09, 97.87 | 98 | 2 | | |

The analytical method is fully validated for the determination of the active substance Imidacloprid in the product.

**Analytical method for the determination of Imidacloprid residues**

Analytical methods for the determination of Imidacloprid residues in soil, water and air have previously been evaluated at EU level and accepted at active substance approval.

Soil

Liquid Chromatography, using Mass Spectrometry for the determination of Imidacloprid

Limit of quantification (LOQ): 0.005 mg/kg

Air

Liquid Chromatography, using UV detection for the determination of Imidacloprid

Limit of quantification (LOQ): 5 µg/m3

Drinking and Surface Water

Liquid Chromatography, using UV detection for the determination of Imidacloprid

Limit of quantification (LOQ): 0.03 µg/L

Methods for monitoring residues in body fluids and tissues and food/feed of plant and animal origin are not necessary, as the active is not classified as toxic or highly toxic regarding human health and the use pattern will not result in contact with food.

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| **Conclusion on the methods for detection and identification of the product** |
| The analytical method is fully validated for the determination of the active substance Imidacloprid in the product.  Analytical methods were provided at EU level for the determination of Imidacloprid residue in soil, water and air with respectively LOQ = 0.005 mg/kg, 5 µg/m3 and 0.03 µg/L.  Imidacloprid is not toxic (T) or very toxic (T+) active substance regarding human health. Therefore, an analytical method in biological matrices is not required.  The product is not intended to be used on surface in contact with food/feed of plant and animal origin, analytical method for the determination of Imidacloprid in food/feed of plant and animal origin is not required. |

### Efficacy against target organisms

#### Function and field of use

PT18 - Insecticides, acaricides and products to control other arthropods (Pest control).

Field of use: Indoors, indoors crack and crevices, outdoors, outdoors crack and crevices, outdoors around buildings, and on nest.

Method: Bait application and non refillable bait box application

DX3 GEL is a ready-for-use bait gel, in syringe and cartridge or in a bait station. It contains the insecticide active substance (PT 18) imidacloprid (0.02% w/w) and is intended to be used for indoors (in crack and crevices and along the walls), outdoors (in crack and crevices, and around buildings), and near nest entrances, by non-professional and professional.

#### Organisms to be controlled and products, organisms or objects to be protected

#### According to the uses claimed by the applicant, DX3 Gel is intented to be used to control:

* Black ant *Lasius niger* (adults and all developmental stages);
* Argentine ant *Linepithema humile* (adults and all developmental stages);
* Pharaoh ant *Monornorium pharaonis* (adults and all developmental stages).

Objects to be protected: Indoor and outdoor of buildings.

Application rates recommended by the applicant are the following:

For the bait gel in syringes or cartridges: 2 drops of 0.05 g each linear meter or per entrance of the nest

For the bait box: 1 bait box every 15-20 m² or per nest entrance.

#### Effects on target organisms, including unacceptable suffering

Imidacloprid is a neonicotinoid which acts on the central nervous system of insects by blockage of the nicotinergic neuronal pathway. This disturbance of the transmission of stimuli leads to paralysis and subsequent death of the target organisms. Imidacloprid acts as a contact insecticide as well as upon ingestion.

#### Mode of action, including time delay

Imidacloprid is a systemic [insecticide](https://en.wikipedia.org/wiki/Insecticide) that acts as an [insect](https://en.wikipedia.org/wiki/Insect) [neurotoxin](https://en.wikipedia.org/wiki/Neurotoxin) and belongs to a class of chemicals called the [neonicotinoids](https://en.wikipedia.org/wiki/Neonicotinoids) which act on the [central nervous system](https://en.wikipedia.org/wiki/Central_nervous_system) of insects. The chemical works by interfering with the transmission of stimuli in the insect nervous system. Specifically, it causes a blockage of the [nicotinergic](https://en.wikipedia.org/wiki/Nicotinic) neuronal pathway. By blocking [nicotinic acetylcholine receptors](https://en.wikipedia.org/wiki/Nicotinic_acetylcholine_receptors), imidacloprid prevents [acetylcholine](https://en.wikipedia.org/wiki/Acetylcholine) from [transmitting](https://en.wikipedia.org/wiki/Neurotransmitter) impulses between nerves, resulting in the insect's paralysis and death. The product controls an ant colony in two weeks after application.

#### Efficacy data

The applicant submitted sixteen studies (semi field and field tests) to show the efficacy of the product DX3 Gel. Twelve of them have shown the efficacy of the bait gel application against three ant species: black ant (*L. niger*), argentin ant (*Linepithemna humile*) and pharaoh ant (*Monomorium pharaonis*).

Four studies (semi field and field tests) showed the efficacy of the bait box application against black ant *Lasius niger.*

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | | | |
| **Function** | **Field of use envisaged** | **Test substance** | **Test organism**  **(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| Insecticide | Indoor  outdoor | DX3 GEL (imidacloprid 0,02 %) Gel in in syringe  Fresh product | *L. niger*  500+/-20 workers from a wild nest | Simulated-Use Test – According to CEB 196 (Method for the assessment of the  efficacy of insecticidal baits against common species of ants – 2011) | Vivarium Trial with 1 nest/trial. The treatment was not repeated along the trial (only 1 application).  1 droplet of 0.05 g was applied by unit by syringe (50 cm long containers).  The same procedure was used but without any treatment for controls.  5 replicates were conducted.  Measures : FCS (Frequency of ants Crossing in Surface) and FCD (Frequency of ants Crossing in Depth).  Time exposure : 28 days.  Vivarium (50 x 40 x 40 cm)  25°C+/-1°C  65%RH+/-4% RH  light 1500 lux 8/16 photoperiod  Food source present | Reduction of activity of test product results:  FCS(28d)= 100%  FCD (28d) = 100%  Queens dead  Number of ants alive at the beginning of the test: 499. Number of ants alive at the end: 0.  Reduction of activity of untreated control results:  FCS (28d) = -6.5%  FCD (28d) = -23.23 %  Queens were alive.  Number of ants alive at the beginning of the test: 503. Number of ants alive at the end: 495.  Palatability (time for the first ant to come and eat the gel) : 15 min.  The test has proved a complete efficacy against black ants *Lasius niger* in the conditions of this simulated-use trial. | 2203-GEL-FRESH-SIM-LN/0317  Serrano,B.(15/05/2017): Simulated use trial of the efficacy of an insecticidal gel bait intended to control ants.  RI:1 |
| Insecticide | Indoor  outdoor | DX3 GEL (imidacloprid 0,02 %) Gel in syringe  aged 3 months (applied under conditions: 25°C-65% RH et lum 1500 lux8/16) | *L. niger*  500+/-20 workers from a wild nest | Simulated-Use Test – According to CEB 196 (Method for the assessment of the  efficacy of insecticidal baits against common species of ants – 2011) | Vivarium Trial with 1 nest/trial. The treatment was not repeated along the trial (only 1 application). 1 droplet of 0.05 g was applied by unit by syringe (50 cm long containers).  The same procedure was used but without any treatment for controls.  5 replicates were conducted.  Measures : FCS (Frequency of ants Crossing in Surface) and FCD (Frequency of ants Crossing in Depth).  Time exposure : 28 days .  Vivarium (50 x 40 x 40 cm)  25°C+/-1°C  65%RH+/-4% RH  light 1500 lux 8/16 photoperiod  Food source present | Reduction of activity of test product results:  FCS(28d)= 100%  FCD (28d) = 100%  Queens dead.  Number of ants alive at the beginning of the test: 506. Number of ants alive at the end: 0.  Reduction of activity of untreated control results:  FCS (28d) = -6.6%  FCD (t0) = -13.8 %  Queens were alive  Number of ants alive at the beginning of the test: 499. Number of ants alive at the end: 477.  Palatability (time for the first ant to come and eat the gel) : 15 minutes.  The test has proved a complete efficacy against black ants *Lasius niger* in the conditions of this simulated-use trial with a 3 months open product. | 2203-GEL-AGED3M-SIM-LN/0317  Serrano,B.(11/08/2017): Simulated use trial of the efficacy of an insecticidal gel bait intended to control ants.  RI:1 |
| Insecticide | Indoor  outdoor | DX3 GEL (imidacloprid 0,02 %) Gel in syringe  3 years aged | *L. niger*  500+/-20 workers from a wild nest | Simulated-Use Test – According to CEB 196 (Method for the assessment of the  efficacy of insecticidal baits against common species of ants – 2011) | Vivarium Trial with 1 nest/trial. The treatment was not repeated along the trial (only 1 application). 1 droplet of 0.05 g was applied by unit by syringe (50 cm long containers).  The same procedure was used but without any treatment for controls.  5 replicates were conducted.  Measures : FCS (Frequency of ants Crossing in Surface) and FCD (Frequency of ants Crossing in Depth).  Time exposure : 28 days.  Vivarium (50 x 40 x 40 cm)  25°C+/-1°C  65%RH+/-4% RH  light 1500 lux 8/16 photoperiod  Food source present | Reduction of activity of test product results:  FCS (28d)= 100%  FCD (28d)= 100 %  Queens dead.  Number of ants alive at the beginning of the test: 502. Number of ants alive at the end: 0.  Reduction of activity of untreated control results:  FCS (28d) = -6.5%  FCD (28d) = -23.23%  Queens were alive.  Number of ants alive at the beginning of the test: 503. Number of ants alive at the end: 495.  Palatability (time for the first ant to come and eat the gel) : 45 minutes.  The test has proved a complete efficacy against black ants *Lasius niger* in the conditions of this simulated-use trial with a 3 years aged product. | 2203-GEL-AGED3Y-SIM-LN/0317  Serrano,B.(15/05/2017): Simulated use trial of the efficacy of an insecticidal gel bait intended to control ants.  RI:1 |
| Insecticide | Indoor  outdoor | DX3 GEL (imidacloprid 0,02 %) 2g Gel in syringe  (Fresh bait) | *L. niger*  wild nests. | Field Test – According to CEB 196 – CEB MG1 – EPPO guidelines. | The sites are chosen according to the following requirements:  - hard surfaces, terraces, pavements, urban environment, houses etc  - Significant external activity of the ants  - Availability of the access along the trial  - Protected sites (not to be damaged)  The treatment was not repeated along the trial (only 1 application).  2 droplets of 0.05 g was applied near the nest entry.  The same procedure was used but without any treatment for controls. 5 replicates were conducted per experimental factor.  Measures : FCS (Frequency of ants Crossing in Surface)  Time exposure : 28 days.  Climatic data :  Month June: 20.7°, Max 37.2°, Min 17.2°, 44 mm rain, 14h of sun.  Month July : 26.4°, Max 28.7°, Min 17.4°, 55 mm rain, 119h of sun. | Reduction of activity of test product results:  FCS (14d)= 95.2%  FCS(28d)= 100%.  Queens dead.  Reduction of activity of untreated control results:  FCS (t0) = -4.7%.  Queens were alive.  The test has proved a complete efficacy against black ants *Lasius niger* within 28 days in the conditions of this field trial. | 2203-BOX-FIELD-LN/0317  Serrano,B.(20/07/2017):  Field assessment of the efficacy of an insecticidal gel bait against ants  RI:1 |
| Insecticide | Indoor  outdoor | DX3 GEL (imidacloprid 0,02 %) Gel in syringe  Fresh product | *L. humile*  500+/-20 workers from a wild nest | Simulated-Use Test – According to CEB 196 (Method for the assessment of the  efficacy of insecticidal baits against common species of ants – 2011) | Vivarium Trial with 1 nest/trial. The treatment was not repeated along the trial (only 1 application). Two doses were tested:  - 1 droplet of 0.05 g per linear meter  - 2 droplets of 0.05 g per linear meter  The treated area was 0.2 m² and 50 cm long, the quantity of product applied in each  replicate was:  - Dose 1: 0.025 g  - Dose 2: 0.05 g  The same procedure was used but without any treatment for controls.  5 replicates were conducted.  Measures : FCS (Frequency of ants Crossing in Surface) and FCD (Frequency of ants Crossing in Depth).  Time exposure : 28 days.  Vivarium (50 x 40 x 40 cm)  25°C+/-1°C  65%RH+/-4% RH  light 1500 lux 8/16 photoperiod  Food source present | Reduction of activity of test product results:  1dropelets:  FCS (28d)= 100%  FCD (28d)= 100%  2 dropelets:  FCS(28d)= 100%  FCD (28d)= 100%  Queens dead.  Number of ants alive at the beginning of the test: 506/502. Number of ants alive at the end: 0.  Reduction of activity of untreated control results:  FCS (28d) = -10%  FCD (28d) = 5.8%  Queens were alive.  Number of ants alive at the beginning of the test: 499. Number of ants alive at the end: 477.  No data for the palatability.  The test has proved a complete efficacy against argentine ants *Linepithema humile* in the conditions of this simulated-use trial. | 2120a/0716  Serrano,B.(15/09/2016)  simulated use trial of the efficacy of an insecticidal gel bait intended to control argentine ants *Linepithema humile*.  RI:1 |
| Insecticide | Outdoor  Indoor | DX3 GEL (imidacloprid 0,02 %) 2g Gel in syringe  aged 3 months (applied under conditions: 25°C-65% RH et lum 1500 lux8/16) | *L. humile*  500+/-20 workers from a wild nest | Simulated-Use Test – According to CEB 196 (Method for the assessment of the  efficacy of insecticidal baits against common species of ants – 2011) | Vivarium Trial with 1 nest/trial. The treatment was not repeated along the trial (only 1 application). 1 droplet of 0.05 g was applied by unit by syringe (50 cm long containers). The same procedure was used but without any treatment for controls.  5 replicates were conducted.  Measures : FCS (Frequency of ants Crossing in Surface) and FCD (Frequency of ants Crossing in Depth).  Time exposure : 28 days.  Vivarium (50 x 40 x 40 cm)  25°C+/-1°C  65%RH+/-4% RH  light 1500 lux 8/16 photoperiod  Food source present | Reduction of activity of test product results:  FCS (28d)= 100%  FCD (28d)= 100%  Queens dead.  Number of ants alive at the beginning of the test: 501. Number of ants alive at the end: 0.  Reduction of activity of untreated control results : FCS (28d) = -3.9%  FCD (28d) = -6.9% Queens were alive  Number of ants alive at the beginning of the test: 499. Number of ants alive at the end: 477.  Palatability (time for the first ant to come and eat the gel) : 30 minutes  The test has proved a complete efficacy against argentine ants *Linepithema humile* in the conditions of this simulated-use trial with a 3 months open product. | 2203-GEL-AGED3M-SIM-LH/0317  Serrano,B.(11/08/2017): Simulated use trial of the efficacy of an insecticidal gel bait intended to control ants *Linepithema humile*.  RI:1 |
| Insecticide | Outdoor  Indoor | DX3 GEL (imidacloprid 0,02 %) 2g Gel in syringe 3 years aged | *L. humile*  500+/-20 workers from a wild nest | Simulated-Use Test – According to CEB 196 (Method for the assessment of the  efficacy of insecticidal baits against common species of ants – 2011) | Vivarium Trial with 1 nest/trial. The treatment was not repeated along the trial (only 1 application). 1 droplet of 0.05 g was applied by unit by syringe (50 cm long containers). The same procedure was used but without any treatment for controls.  5 replicates were conducted.  Measures : FCS (Frequency of ants Crossing in Surface) and FCD (Frequency of ants Crossing in Depth).  Time exposure : 28 days.  Vivarium (50 x 40 x 40 cm)  25°C+/-1°C  65%RH+/-4% RH  light 1500 lux 8/16 photoperiod  Food source present | Reduction of activity of test product results:  FCS (28d)= 100%  FCD (28d)= 100%  Queens dead.  Number of ants alive at the beginning of the test: 501. Number of ants alive at the end: 0.  Reduction of activity of untreated control results : FCS (28d) = -2.1%  FCD (28d) = -33.1 % Queens were alive.  Number of ants alive at the beginning of the test: 499. Number of ants alive at the end: 491.  Palatability (time for the first ant to come and eat the gel): 60 minutes  The test has proved a complete efficacy against argentine ants *Linepithema humile* in the conditions of this simulated-use trial with a 3 years aged product. | 2203-GEL-AGED3Y-SIM-LH/0317  Serrano,B.(15/05/2017)  simulated use trial of the efficacy of an insecticidal gel bait intended to control ants *Linepithema humile*.  RI:1 |
| Insecticide | Indoor  Outdoor | DX3 GEL (imidacloprid 0,02) 2g Gel in syringe (Fresh bait) | *L. humile*  wild nests. | Field Test – According to CEB 196 – CEB MG1 – EPPO guidelines. | The sites are chosen according to the following requirements:  - hard surfaces, terraces, pavements, urban environment, houses etc  - significant external activity of the ants  - availability of the access along the trial  - protected sites (not to be damaged)  The treatment was not repeated along the trial (only 1 application). 2 droplets of 0.05 g was applied near the nest entry.  The same procedure was used but without any treatment for controls.  5 replicates were conducted per experimental factor.  Measures : FCS (Frequency of ants Crossing in Surface)  Time exposure : 28 days.  Climatic data :  Month September: 20.4°, Max 38.7°, Min 15.4°, 124.1 mm rain, 214h of sun.  Month October : 19.5°, Max 25.1°, Min 12.6°, 38.8 mm rain, 63h of sun. | Reduction of activity of test product results :  FCS (14d)= 98.9%  FCS (28d)= 100%  Reduction of activity of untreated control results : FCS (28d) = 10.9%  The test has proved a complete efficacy against argentine ants *Linepithema humile* within 28 days in the conditions of this field trial. | 2120b/0716  Serrano,B.(17/10/2016):  Field assessment of the efficacy of an insecticidal baits against argentine ants.  RI:1 |
| Insecticide | Outdoor  Indoor | DX3 GEL (imidacloprid 0,02 %) Gel in syringe  Fresh product | *M. pharaonis*  500+/-20 workers from a wild nest | Simulated-Use Test – According to CEB 196 (Method for the assessment of the  efficacy of insecticidal baits against common species of ants – 2011) | Vivarium Trial with 1 nest/trial. The treatment was not repeated along the trial (only 1 application). 1 droplet of 0.05 g was applied by unit by syringe (50 cm long containers). The same procedure was used but without any treatment for controls.  5 replicates were conducted.  Measures : FCS (Frequency of ants Crossing in Surface) and FCD (Frequency of ants Crossing in Depth).  Time exposure : 28 days.  Vivarium (50 x 40 x 40 cm)  25°C+/-1°C  65%RH+/-4% RH  light 1500 lux 8/16 photoperiod  Food source present | Reduction of activity of test product results:  FCS (28d)= 100%  FCD (28d) = 100%  Queens dead.  Number of ants alive at the beginning of the test: 497. Number of ants alive at the end: 0.  Reduction of activity of untreated control results : FCS (28d) = -0.25%  FCD (28d) = -11.6 %  Queens were alive  Number of ants alive at the beginning of the test: 508. Number of ants alive at the end: 491.  Palatability (time for the first ant to come and eat the gel) : 15 minutes  The test has proved a complete efficacy against pharaoh ants *Monomorium pharaonis* in the conditions of this simulated-use trial. | 2203-GEL-FRESH-SIM-MP/0317  Serrano,B.(15/05/2017)  simulated use trial of the efficacy of an insecticidal gel bait intended to control ants *Monomorium pharaonis.*  RI:1 |
| Insecticide | Outdoor  Indoor | DX3 GEL (imidacloprid 0,02 %) Gel in syringe  aged 3 months (applied under conditions: 25°C-65% RH et lum 1500 lux8/16) | *M. pharaonis*  500+/-20 workers from a wild nest | Simulated-Use Test – According to CEB 196 (Method for the assessment of the  efficacy of insecticidal baits against common species of ants – 2011) | Vivarium Trial with 1 nest/trial. The treatment was not repeated along the trial (only 1 application). 1 droplet of 0.05 g was applied by unit by syringe (50 cm long containers). The same procedure was used but without any treatment for controls.  5 replicates were conducted.  Measures : FCS (Frequency of ants Crossing in Surface) and FCD (Frequency of ants Crossing in Depth).  Time exposure : 28 days.  Vivarium (50 x 40 x 40 cm)  25°C+/-1°C  65%RH+/-4% RH  light 1500 lux 8/16 photoperiod  Food source present | Reduction of activity of test product results: FCS(28d)= 100%  FCD (28d) = 100%  Queens dead.  Number of ants alive at the beginning of the test: 500. Number of ants alive at the end: 0.  Reduction of activity of untreated control results : FCS (28d) = 0.58%  FCD (28d) = 1.4 % Queens were alive  Number of ants alive at the beginning of the test: 499. Number of ants alive at the end: 491.  Palatability (time for the first ant to come and eat the gel) : 30 minutes  The test has proved a complete efficacy against pharaoh ants *Monomorium pharaonis* in the conditions of this simulated-use trial with a 3 months open product. | 2203-GEL-AGED3M-SIM-MP/0317  Serrano,B.(11/08/2017): Simulated use trial of the efficacy of an insecticidal gel bait intended to control ants *Monomorium pharaonis.*  RI:1 |
| Insecticide | Outdoor Indoor | DX3 GEL (imidacloprid 0,02 %) Gel in syringe  3 years aged | *M. pharaonis*  500+/-20 workers from a wild nest | Simulated-Use Test – According to CEB 196 (Method for the assessment of the  efficacy of insecticidal baits against common species of ants – 2011) | Vivarium Trial with 1 nest/trial. The treatment was not repeated along the trial (only 1 application). 1 droplet of 0.05 g was applied by unit by syringe (50 cm long containers). The same procedure was used but without any treatment for controls.  5 replicates were conducted.  Measures : FCS (Frequency of ants Crossing in Surface) and FCD (Frequency of ants Crossing in Depth).  Time exposure : 28 days.  Vivarium (50 x 40 x 40 cm)  25°C+/-1°C  65%RH+/-4% RH  light 1500 lux 8/16 photoperiod  Food source present | Reduction of activity of test product results:  FCS(28d)= 100%  FCD (28d) = 100%  Queens dead.  Number of ants alive at the beginning of the test: 500. Number of ants alive at the end: 0.  Reduction of activity of untreated control results : FCS (28d) = -0.25 %  FCD (28d) = -11.6 % Queens was alive  Number of ants alive at the beginning of the test: 499. Number of ants alive at the end: 491.  Palatability (time for the first ant to come and eat the gel) : 60 minutes  The test has proved a complete efficacy against pharaoh ants *Monomorium pharaonis* in the conditions of this simulated-use trial with a 3 years aged product. | 2203-GEL-AGED3Y-SIM-MP/0317  Serrano,B.(15/05/2017)  simulated use trial of the efficacy of an insecticidal gel bait intended to control ants *Monomorium pharaonis.*  RI:1 |
| Insecticide | Indoor  Outdoor | DX3 GEL (imidacloprid 0,02) Gel in syringe (Fresh bait) | *M.pharaonis*  wild nests | Field Test – According to CEB 196 – CEB MG1 – EPPO guidelines. | The sites are chosen according to the following requirements:  - hard surfaces, terraces, pavements, urban environment, houses etc  - significant external activity of the ants  - availability of the access along the trial  - protected sites (not to be damaged)  The treatment was not repeated along the trial (only 1 application). 2 droplets of 0.05 g was applied near the nest entry.  The same procedure was used but without any treatment for controls.  5 replicates were conducted per experimental factor.  Measures : FCS (Frequency of ants Crossing in Surface)  Time exposure : 28 days.  Climatic data :  Month June: 20.7°, Max 37.2°, Min 17.2°, 44 mm rain, 14h of sun.  Month July : 26.4°, Max 28.7°, Min 17.4°, 55 mm rain, 119h of sun. | Reduction of activity of test product results :  FCS (14d)= 100%  FCS(28d)= 100%  Queens dead.  Reduction of activity of untreated control results : FCS (28d) = -19.7%  The test has proved a complete efficacy against pharaoh ants *Monomorium pharaonis* within 28 days in the conditions of this field trial. | 2203-GEL-FIELD-MP/0317  Serrano,B.(20/07/2017):  Field assessment of the efficacy of an insecticidal gel bait against ants.  RI:1 |
| Insecticide | Outdoor  Indoor | DX3 GEL (imidacloprid 0,02 %)  2 g Gel in bait box  Fresh product | *L. niger*  500+/-20 workers from a wild nest | Simulated-Use Test – According to CEB 196 (Method for the assessment of the  efficacy of insecticidal baits against common species of ants – 2011) | Vivarium Trial with 1 nest/trial. The treatment was not repeated along the trial (only 1 application). 1 bait box/nest.  The same procedure was used but without any treatment for controls.  5 replicates were conducted.  Measures : FCS (Frequency of ants Crossing in Surface) and FCD (Frequency of ants Crossing in Depth).  Time exposure : 28 days.  Vivarium (50 x 40 x 40 cm)  25°C+/-1°C  65%RH+/-4% RH  light 1500 lux 8/16 photoperiod  Food source present | Reduction of activity of test product results: FCS(28d)= 100%  FCD (28d) = 100%  Queens dead.  Number of ants alive at the beginning of the test: 506. Number of ants alive at the end: 0.  Reduction of activity of untreated control results : FCS (28d) = -6.5%  FCD (28d) = -23.2% Queens were alive.  Number of ants alive at the beginning of the test: 503. Number of ants alive at the end: 495.  Palatability (time for the first ant to come and eat the gel) : 15 minutes  The test has proved a complete efficacy against black ants *Lasius niger* in the conditions of this simulated-use trial. | 2203-BOX-FRESH-SIM-LN/0317R  Serrano,B.(15/05/2017): Simulated use trial of the efficacy of an insecticidal gel bait intended to control ants *Lasius niger*  RI:1 |
| Insecticide | Outdoor Indoor | DX3 GEL (imidacloprid 0,02 %)  2 g Gel in bait box  aged 3 months (opened under conditions: 25°C-65% RH et lum 1500 lux8/16) | *L. niger*  500+/-20 workers from a wild nest | Simulated-Use Test – According to CEB 196 (Method for the assessment of the  efficacy of insecticidal baits against common species of ants – 2011) | Vivarium Trial with 1 nest/trial. The treatment was not repeated along the trial (only 1 application). 1 bait box/nest.  The same procedure was used but without any treatment for controls.  5 replicates were conducted.  Measures : FCS (Frequency of ants Crossing in Surface) and FCD (Frequency of ants Crossing in Depth).  Time exposure : 28 days.  Vivarium (50 x 40 x 40 cm)  25°C+/-1°C  65%RH+/-4% RH  light 1500 lux 8/16 photoperiod  Food source present | Reduction of activity of test product results : FCS(28d)= 100% activity.  FCD (28d) = 100%  Queens dead.  Number of ants alive at the beginning of the test: 502. Number of ants alive at the end: 0.  Reduction of activity of untreated control results : FCS (28d) = -6.6 %  FCD (28d) = -13.8% Queens were alive.  Number of ants alive at the beginning of the test: 501. Number of ants alive at the end: 487.  Palatability (time for the first ant to come and eat the gel): 15 minutes  The test has proved a complete efficacy against black ants *Lasius niger* in the conditions of this simulated-use trial with a 3 months open product. | 2203-BOX-AGED3M-SIM-LN/0317  Serrano,B.(11/08/2017): Simulated use trial of the efficacy of an insecticidal gel bait intended to control ants *Lasius niger*  RI:1 |
| Insecticide | Outdoor Indoor | DX3 GEL (imidacloprid 0,02 %)  2 g Gel in bait box  3 years aged | *L. niger*  500+/-20 workers from a wild nest | Simulated-Use Test – According to CEB 196 (Method for the assessment of the  efficacy of insecticidal baits against common species of ants – 2011) | Vivarium Trial with 1 nest/trial. The treatment was not repeated along the trial (only 1 application). 1 bait box/nest.  The same procedure was used but without any treatment for controls.  5 replicates were conducted.  Measures : FCS (Frequency of ants Crossing in Surface) and FCD (Frequency of ants Crossing in Depth).  Time exposure : 28 days.  Vivarium (50 x 40 x 40 cm)  25°C+/-1°C  65%RH+/-4% RH  light 1500 lux 8/16 photoperiod  Food source present | Reduction of activity of test Product results : FCS(28d)= 100%  FCD (28D) = 100%  Queens dead.  Number of ants alive at the beginning of the test: 502. Number of ants alive at the end: 0.  Reduction of activity of untreated results :  FCS (28d) = -6.5%  FCD (28d) = -23.2% Queens were alive. Number of ants alive at the beginning of the test: 503. Number of ants alive at the end: 495.  Palatability (time for the first ant to come and eat the gel) : 60 minutes  The test has proved a complete efficacy against black ants *Lasius niger* in the conditions of this simulated-use trial with a 3 years aged product. | 2203-BOX-AGED3Y-SIM-LN/0317  Serrano,B.(15/05/2017): Simulated use trial of the efficacy of an insecticidal gel bait intended to control ants *Lasius niger*  RI:1 |
| Insecticide | Indoor  Outdoor | DX3 GEL (imidacloprid 0,02 %)  2g Gel in bait box (Fresh bait) | *L. niger*  wild nests. | Field Test – According to CEB 196 – CEB MG1 – EPPO guidelines. | The sites are chosen according to the following requirements:  - hard surfaces, terraces, pavements, urban environment, houses etc  - significant external activity of the ants  - availability of the access along the trial  - protected sites (not to be damaged)  The treatment was not repeated along the trial (only 1 application). 1 bait box applied/nest (nest entry).  The same procedure was used but without any treatment for controls.5 replicates were conducted per experimental factor.  Measures : FCS (Frequency of ants Crossing in Surface)  Time exposure : 28 days.  Climatic data :  Month June: 20.7°, Max 37.2°, Min 17.2°, 44 mm rain, 14h of sun.  Month July : 26.4°, Max 28.7°, Min 17.4°, 55 mm rain, 119h of sun. | Reduction of activity of test product results :  FCS (14d)= 95.7%  FCS(28d)= 100%  Queens dead.  Reduction of activity of untreated control results : FCS (28d) = -4.7 % Queens were alive.  The test has proved a complete efficacy against black ants *Lasius niger* within 28 days in the conditions of this field trial. | 2203-BOX-FIELD-LN/0317  Serrano,B.(20/07/2017):  Field assessment of the efficacy of an insecticidal gel bait against *Lasius niger* ants  RI:1 |

The efficacy data submitted are compliant with the requirements of TNsG PT 18 (2012) for bait product intended to be used against ants: palatability and mortality are demonstrated in both semi field and field tests. Therefore, the efficacy of the bait has been proved for the shelf life of 3 years when applied:

* As gel bait (drops) against black ant (*L. niger*), argentin ant (*Linepithema humile*) and pharaoh ant (*Monomorium pharaonis*)
* in boxes against black ant *(L. niger)*

|  |
| --- |
| **Conclusion on the efficacy of the product** |
| In accordance with the submitted tests and the requirements of the TNsG on product evaluation for PT18 (2012), the bait product DX3 GEL (0.02 % w/w imidacloprid) has shown sufficient efficacy:   * as gel bait (drops) in syringes or cartridges at a dose of 2 drops of 0.05 g per linear meter or per nest entrance for the control of garden ants (*Lasius niger*), argentine ant (*Linepithema humile*) and pharaoh ant (*Monomorium pharaonis*) until 3 months after application and with a shelf life of 3 years. The product control the population (with death of queen) and is effective within two weeks after application. * as bait box at a dose of 1 bait every 15-20 m² or per nest entrance for the control of garden ants (*Lasius niger*) until 3 months after opening and with a shelf life of 3 years. The product control the population (with death of queen) and is effective within two weeks after application.   It has to be noted that no specific crack and crevices test has been submitted because it was considered at the submission of this dossier (2018) that such application was cover by surface treatment.  Nevertheless, to take into account recent WG discussions, in case of an application for a change or at the renewal of authorisation, new crack and crevices trials should be requested to confim the efficacy of the product DX3 GEL for this mode of application. |

#### Occurrence of resistance and resistance management

No resistance phenomena occurred during product testing. Furthermore, no resistance to imidacloprid has been reported in ants so far. In order to avoid the occurrence of resistance to any active ingredient, products with different modes of action should be used in alternation and the frequent repeated use of the same a.i. should be avoided.

To ensure a satisfactory level of efficacy and avoid the development of resistance, the recommendations proposed in the SPC have to be implemented.

#### Known limitations

There are no known limitations.

#### Evaluation of the label claims

French competent authorities (FR CA) assessed that the product DX3 GEL, has shown a sufficient efficacy for the following uses claimed:

* Use as gel bait (drops) against garden ants (*Lasius niger*), argentine ant (*Linepithema humile*) and pharaoh ant (*Monomorium pharaonis*) at the application rate of 2 drops of 0.05 g each per linear meter or per nest entrance, until 3 months after application and with a shelf life of 3 years. The product control the population (with death of queen) and is effective in two weeks after application.
* Use as bait box against garden ants (*Lasius niger*) at the application rate of 1 bait box every 15-20 m² or per nest entrance, until 3 months after opening and with a shelf life of 3 years. The product control the population (with death of queen) and is effective in two weeks after application.

#### Relevant information if the product is intended to be authorised for use with other biocidal product(s)

The biocidal product is not intended to be used with other products including other biocidal products.

### Risk assessment for human health

In order to avoid unnecessary animal experiment, no study was conducted. Classification is determined by using the calculation method described in the Guidance on the Application of the CLP Criteria Version 5.0 (July 2017), based on the available data on each component. According to the composition and the MSDS of each component, the product DX3 GEL is not classified for acute toxicological properties.

#### Assessment of effects on Human Health

***Skin corrosion and irritation***

No skin irritation/corrosion study was conducted. Classification is based on the available data on each component.

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Skin corrosion and irritation** | |
| Value/conclusion | Not corrosive/irritating to the skin. |
| Justification for the value/conclusion | According to the composition, none of the component is toxicologically relevant for skin irritation or corrosion. |
| Classification of the product according to CLP | Not classified according to Regulation (EC) N°1272/2008. |

***Eye irritation***

No eye irritation/corrosion study was conducted. Classification is based on the available data on each component.

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Eye irritation** | |
| Value/conclusion | Not irritating to the eye. |
| Justification for the value/conclusion | According to the composition, none of the component is toxicologically relevant for eye irritation or corrosion. |
| Classification of the product according to CLP | Not classified according to Regulation (EC) N°1272/2008. |

***Respiratory tract irritation***

No study of respiratory tract irritation is available. Classification is based on the available data on each component.

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| --- | --- |
| **Conclusion used in the Risk Assessment – Respiratory tract irritation** | |
| Classification of the product according to CLP | Not classified according to Regulation (EC) N°1272/2008. |

***Skin sensitization***

Skin sensitization study was not conducted. Classification is based on the available data on each component.

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Skin sensitisation** | |
| Value/conclusion | Not sensitising to the skin. |
| Justification for the value/conclusion | According to the composition, none of the component is toxicologically relevant for skin sensitisation. |
| Classification of the product according to CLP | Not classified according to Regulation (EC) N°1272/2008. |

***Respiratory sensitization (ADS)***

No study of respiratory tract sensitisation is available. Classification is based on the available data on each component.

|  |  |
| --- | --- |
| **Conclusion** **used in Risk Assessment – Respiratory sensitisation** | |
| Value/conclusion | Not sensitising to the respiratory system. |
| Justification for the value/conclusion | According to the composition, none of the component is toxicologically relevant for respiratory sensitisation. |
| Classification of the product according to CLP | Not classified according to Regulation (EC) N°1272/2008. |

***Acute toxicity***

*Acute toxicity by oral route*

No acute toxicity studies were conducted. Classification is based on the available data on each component (oral, inhalation and dermal route).

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute oral toxicity** | |
| Value | Not acutely toxic via the oral route. |
| Justification for the selected value | The classification has been determined using the calculation method.  According to the composition, none of the component is toxicologically relevant for acute oral toxicity. |
| Classification of the product according to CLP | Not classified according to Regulation (EC) N°1272/2008. |

*Acute toxicity by inhalation*

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute inhalation toxicity** | |
| Value | Not acutely toxic via inhalation. |
| Justification for the selected value | The classification has been determined using the calculation method.  According to the composition, none of the component is toxicologically relevant for acute toxicity by inhalation. |
| Classification of the product according to CLP | Not classified according to Regulation (EC) N°1272/2008. |

*Acute toxicity by dermal route*

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute dermal toxicity** | |
| Value | Not acutely toxic via the dermal route. |
| Justification for the selected value | The classification has been determined using the calculation method.  According to the composition, none of the component is toxicologically relevant for acute dermal toxicity. |
| Classification of the product according to CLP | Not classified according to Regulation (EC) N°1272/2008. |

***Information on dermal absorption***

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Dermal absorption** | |
| Substance | Imidacloprid |
| Value | 70 % |
| Justification for the selected value | According to Guidance on dermal absorption (EFSA, 2017), page 19: “Gel baits or slug pellets, for example, should be categorised as ‘other’ because these are ready for use (RB) formulations and the compositions are clearly different from solid formulations”. Therefore, a default dermal absorption value of 70% may be applied for other types of formulations. |

***Available toxicological data relating to non active substance(s) (i.e. substance(s) of concern)***

No substance of concern has been identified.

#### Exposure assessment

DX3 GEL is a ready-to-use insecticide for the control of ants (2 drops of 0.05 g each linear meter) and for nest (maximum 30 drops of 0.05 g/nest). The product is used with syringes, cartridges and packaged in bait boxes for professionals and non-professionals users.

**Identification of main paths of human exposure towards active substance and substances of concern from its use in biocidal product**

| **Summary table: relevant paths of human exposure** | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Exposure path** | **Primary (direct) exposure** | | | **Secondary (indirect) exposure** | | | |
| **Industrial use** | **Professional use** | **Non-professional use** | **Industrial use** | **Professional use** | **General public** | **Via food** |
| Inhalation | n.a. | No | No | n.a. | No | No | No |
| Dermal | n.a. | Yes | Yes | n.a. | No | Yes | No |
| Oral | n.a. | No | No | n.a. | No | Yes | No |

*n.a.: not applicable*

*Primary exposure:*

Professionals and non-professionals may be exposed during application when touching the drops of gel. Exposure of bait boxes is covered in this scenario.

Inhalation is considered negligible regarding the low vapour pressure of active substance (4E-10 Pa at 20ºC) and application method of the gel.

*Secondary exposure:*

After application, indirect dermal contact may occur when touching the drops of gel. Infants may be incidentally exposed orally to DX3 GEL via hand-to-mouth behaviour. Therefore, oral and dermal exposures are taken into consideration for secondary exposure.

Inhalation is considered negligible regarding the low vapour pressure of active substance (4E-10 Pa at 20ºC) and application method of the gel.

Chronic secondary exposure is not expected.

Exposure of bait boxes is covered in this scenario.

***List of scenarios***

| **Summary table: scenarios** | | | |
| --- | --- | --- | --- |
| **Scenario number** | **Scenario** | **Primary or secondary exposure**  **Description of scenario** | **Exposed group** |
| 1. | Application (syringe/cartridge) | **Primary exposure – dermal exposure**  Dermal contact during application | Professionals |
| 2. | Application (syringe/cartridge) | **Primary exposure – dermal exposure**  Dermal contact during application | Non professionals |
| 3. | Post-application – indirect dermal contact | **Secondary exposure – dermal exposure**  After application, indirect dermal contact may occur when touching the drops of gel. | Bystanders (toddlers and infants) |
| 4. | Post-application – ingestion of the product | **Secondary exposure – oral exposure**  The product may be ingested by a child or an infant when it is placed in a treated area | Bystanders (toddlers and infants) |

***Industrial exposure***

DX3 GEL is used by professionals and non-professionals indoors. No industrial exposure is foreseen.

***Professional exposure***

*Scenario [1] - Application (syringe/cartridge)*

| **Description of Scenario [1]** |
| --- |
| According to the Imidacloprid CAR, a mathematical methodology is proposed to assess the exposition. Direct exposure taking into account the number of operations may be questionable for the professionals; indeed it could be possible to have more than 5 times opening and 5 times sealing of cartridge during the day.  In this context, a reverse scenario is considered more relevant for the estimation of exposure of DX3 GEL than proposed in the CAR of Imidacloprid.  A reverse scenario approach is done to assess the amount of product needed to reach the AEL for a professional user, with the following parameters for dermal exposure:   |  |  |  | | --- | --- | --- | | **Parameters** | **Value** | **Reference** | | AELlong-term | 0.06 | CAR 2013 | | Concentration of imidacloprid | 0.0204% | Applicant’s data | | Dermal absorption | 70% | Default value (EFSA 2017) | | Adult body weight (kg) | 60 | HEAd Hoc Recommendation no. 14 | |

**Calculations for Scenario [1]**

Maximum quantity to reach the AELlong-term is equal to 25.2 g of the product that would be necessary for a professional user to generate systemic effects due to the dermal primary exposure. This quantity corresponds to 1 total syringe or ½ cartridge. It is very unlikely that such a high amount of product comes in direct contact with the skin of the user during application. Dermal exposure can be considered as acceptable without gloves.

***Non-professional exposure***

*Scenario [2] – Application (syringe/cartridge)*

| **Description of Scenario [2]** |
| --- |
| According to the Imidacloprid CAR, a mathematical methodology is proposed to assess the exposition. Direct exposure taking into account the number of operations may be questionable for the professionals; indeed it could be possible to have more than 5 times opening and 5 times sealing of cartridge during the day.  In this context, a reverse scenario is considered more relevant for the estimation of exposure of DX3 GEL than proposed in the CAR of Imidacloprid.  A reverse scenario approach is done to assess the amount of product needed to reach the AEL for a non-professional user, with the following parameters for dermal exposure:   |  |  |  | | --- | --- | --- | | **Parameters** | **Value** | **Reference** | | AELmedium-term | 0.2 | CAR 2013 | | Concentration of imidacloprid | 0.0204% | Applicant’s data | | Dermal absorption | 70% | Default value (EFSA 2017) | | Adult body weight (kg) | 60 | HEAd Hoc Recommendation no. 14 | |

**Calculations for Scenario [2]**

Maximum quantity to reach the AELmedium-term is equal to 84.0 g of the product that would be necessary for a non-professional user to generate systemic effects due to the dermal primary exposure. This quantity corresponds to 3 syringes or 3 cartridges. It is very unlikely that such a high amount of product comes in direct contact with the skin of the user during application. Dermal exposure can be considered as acceptable.

***Exposure of the general public***

*Scenario [3]- Secondary exposure - indirect dermal contact*

| **Description of Scenario [3]** | | | |
| --- | --- | --- | --- |
| After application, indirect dermal contact may occur when touching the drops of gel. A dermal exposure is taken into account for toddlers and infants, with a surface area of 1 m² (worst-case value as the product should be placed out of reach of children). As indicated in the CAR, secondary exposure of professionals after application of gel is not expected.  In addition, a reverse scenario has been used to estimate the quantity of product that an infant or toddler should touch to reach the AELmedium-term for syringe and cartridge application. Considering 0.05 g/nest and 8 drops/m², the following quantities of DX3 GEL are considered:   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | |  | Body weight | Quantity of product to touch to reach the AELmedium-term (g) | Quantity of product to touch to reach the AEL medium-term (in number of tubes containing 5 or 50 g gel) | Number of drops | Surface area (m²) | | Toddler | 10 | 14.0 | 2 syringes of 5g | 281 | 35.0 | | Infant | 8 | 11.2 | 2 syringes of 5g | 225 | 28.0 | | | | |
|  | Parameters | Value | References |
| Tier 1 | Concentration of imidacloprid | 0.0204% | Applicant’s data |
| In-use dose (g/m²) | 1.5 | Applicant’s data |
|  | Surface area to be touched (m²) | 1 | Worst-case (considering that the product will be placed out of reach of children and infants) |
|  | Dermal absorption | 70% | Default value (EFSA 2017) |
|  | Infant body weight (kg) | 8 | HEAd Hoc Recommendation no.14 |
|  | Toddler body weight (kg) | 10 | HEAd Hoc Recommendation no.14 |

**Calculations for Scenario [3]**

| **Summary table: systemic exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake**  (mg/kg bw/d) | **Estimated oral uptake**  (mg/kg bw/d) | **Estimated total uptake**  (mg/kg bw/d) |
| Scenario [3] – toddler | 1/no PPE | n.a | 2.14E-02 | - | 2.14E-02 |
| Scenario [3] – infant | 1/no PPE | n.a | 2.68E-02 | - | 2.68E-02 |

Reverse scenario: Maximum quantity to reach the AELmedium-term is equal to 14.0 and 11.2 g for toddlers and infants, respectively, which are equivalent to 2 syringes of 5 g. The exposure to such amount of product is not likely to occur, then it can be considered as acceptable.

*Scenario [4] - Secondary exposure - ingestion*

| **Description of Scenario [4]** | | | |
| --- | --- | --- | --- |
| Toddlers and infants will play on the floor and are identified as a group at risk through secondary exposure. At 6-12 months of age, mouthing behaviour is most extensive (TNsG 2002). In this context, they may be incidentally exposed orally to DX3 GEL via hand-to-mouth behaviour. Even if the product contains a bittering agent, an oral exposure is taken account, with a hand-to-mouth transfer of 10% and a surface area of 1 m². | | | |
|  | Parameters | Value | Reference |
| Tier 1 | Concentration of imidacloprid | 0.0204% | Applicant’s data |
| In-use dose (g/m²) | 1.5 | Applicant’s data |
| Surface area to be touched (m²) | 1 | Worst-case (considering that the product will be placed out of reach of children and infants) |
| Hand-to-mouth contact | 10% | Assumption of the calculated external dermal exposure is ingested, see HEEG opinion 7 |
| Oral absorption | 100% | Worst-case value (CAR: 90%) |
| Infant body weight (kg) | 8 | HEAd Hoc Recommendation no.14 |
| Toddler body weight (kg) | 10 | HEAd Hoc Recommendation no.14 |

**Calculations for Scenario [4]**

| **Summary table: systemic exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake** (mg/kg bw/d) | **Estimated oral uptake** (mg/kg bw/d) | **Estimated total uptake**  (mg/kg bw/d) |
| Scenario [4] - toddler | 1/no PPE | n.a | - | 3.06E-03 | 3.06E-03 |
| Scenario [4] - infant | 1/no PPE | n.a | - | 3.83E-03 | 3.83E-03 |

***Dietary exposure***

The biocidal product is not intended for direct application to food or feeding stuff or to surfaces and areas where food or feeding stuff are prepared or stored. Hence, no exposure of food and feeding stuff to a.s. is expected when applied according to the recommended uses. Additional food or feeding stuffs studies are not required.

*Information of non-biocidal use of the active substance*

The active substance imidacloprid is approved as an insecticide under regulation (EC) No 1107/2009. European Commission Implementing Regulation (EU) 2018/783 has restricted the use of plant protection products containing imidacloprid to greenhouse crops to ensure protection of bees The EU pesticide database lists MRL values from 0.05 to 5 mg/kg. Considering the proposed PT18 biocidal use of the active substance imidacloprid as an ant gel bait, no MRL exceedance is expected.

| **Summary table of other (non-biocidal) uses** | | | |
| --- | --- | --- | --- |
|  | **Sector of use1** | **Intended use** | **Reference value(s) 2**  **expressed as imidacloprid** |
| 1. | Plant protection  products | Insecticide (authorised under Reg.  1107/2009) | MRL range of 0.05 – 5 mg/kg imidacloprid (Reg. (EU) No 491/2014) |

1 e.g. plant protection products, veterinary use, food or feed additives

2 e.g. MRLs. Use footnotes for references.

***Summary of exposure assessment***

| **Scenarios and values to be used in risk assessment** | | | |
| --- | --- | --- | --- |
| **Scenario number** | **Exposed group** | **Tier/PPE** | **Estimated total uptake** |
| 1. | Professionals | 1/no PPE | Maximum quantity to be touched: 25.2 g (1 total syringe or ½ cartridge) |
| 2. | Non-professionals | 1/no PPE | Maximum quantity to be touched: 84.0g  (3 syringes or 3 cartridges) |
| 3. | Bystanders – toddler  Dermal | 1/no PPE | 2.14E-02 mg/kg bw/d |
| 3. | Bystanders – infant  Dermal | 1/no PPE | 2.68E-02 mg/kg bw/d |
| 4. | Bystanders – toddler  Ingestion | 1/no PPE | 3.06E-03 mg/kg bw/d |
| 4. | Bystanders – infant  Ingestion | 1/no PPE | 3.83E-03 mg/kg bw/d |

#### Risk characterisation for human health

Reference values to be used in Risk Characterisation

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Reference** | **Study** | **NOAEL (LOAEL)** | **AF1** | **Correction for oral absorption** | **Value** |
| AELshort-term | 28-day oral toxicity study in dogs | 40 | 100 | - | 0.4 |
| AELmedium-term | dog 90-day and rabbit developmental studies | 20 | 100 | - | 0.2 |
| AELlong-term | 2-year study in rats | 6 | 100 | - | 0.06 |
| ARfD | Not relevant |  |  |  |  |
| ADI | Not relevant |  |  |  |  |

1 10 x 10 for inter- and intra-species.

**Maximum residue limits or equivalent**

The active substance imidacloprid is approved as an insecticide under regulation (EC) No 1107/2009. MRLs are set up on food commodities, and their values must be respected. Considering the proposed PT18 biocidal use of the active substance imidacloprid as an ant gel bait, no MRL exceedance is expected.

|  |  |  |  |
| --- | --- | --- | --- |
| **MRLs or other relevant reference values** | **Reference** | **Relevant commodities** | **Value**  **expressed as imidacloprid** |
| **MRL** | Reg. (EU) No 491/2014 | Raw food commodities | range from 0.05 to 5 mg/kg |

***Risk for industrial users***

DX3 GEL is not intended by industrial users.

***Risk for professional users***

The maximum quantity to reach the AELlong-term is equal to 25 g of the product and would be necessary for a professional user to generate systemic effects due to the dermal exposure. This quantity corresponds to 1 total syringe or ½ cartridge. The exposure to such amount of product is not likely to occur, then the risk for professional users is considered as acceptable without gloves.

***Risk for non-professional users***

The maximum quantity to reach the AELmedium-term is equal to 84 g of the product and would be necessary for a non-professional user to generate systemic effects due to the dermal exposure. This quantity corresponds to 3 syringes or 3 cartridges.

The exposure to such amount of product is not likely to occur, then the risk for non-professional users is considered as acceptable.

***Risk for the general public***

Systemic effects

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **Systemic NOAEL**  **mg/kg bw/d** | **AEL**  **mg/kg bw/d** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL**  **(%)** | **Acceptable**  **(yes/no)** |
| Scenario [3] – infant (dermal route) | 1 | 20 | 0.2 | 2.68E-02 | 13.4% | Yes |
| Scenario [3] – toddler (dermal route) | 1 | 20 | 0.2 | 2.14E-02 | 10.7% | Yes |
| Scenario [4] – infant (oral route) | 1 | 20 | 0.2 | 3.83E-03 | 1.9% | Yes |
| Scenario [4] – toddler (oral route) | 1 | 20 | 0.2 | 3.06E-03 | 1.5% | Yes |

**Conclusion**

The infant exposed by the oral route represents the worst case scenario. A reverse scenario was performed. The maximum quantity to reach the AELmedium-term by ingestion for infants is equal to 157 drops which is equivalent to a surface area of 19.6 m2.

Considering the following RMM: “Apply the product safely in areas not accessible to children, pets and non-target animals”, the exposure to such amount of product is not likely to occur and thus the risk is considered acceptable for infant.

***Risk for consumers via residues in food***

Considering the proposed PT18 biocidal use of the active substance imidacloprid as an ant gel bait, no risk for consumers via residues in food are expected to occur. Indeed, label instruction clearly states that the product should be applied away from food, drink source or feeding stuffs: “Do not apply directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and animals.”

Moreover, the application of the product in cracks and crevices will limit the possible food contamination occurrence.

### Risk assessment for animal health

The following RMM is proposed: “Apply the product safely in areas not accessible to children, pets and non-target animals”.

### Risk assessment for the environment

All the following endpoints are intended to be treated in compliance with confidential rules of BPR regulation.

|  |
| --- |
| Infobox 1- FR CA position:  **FR CA:** The following risk assessment for the environment has been submitted by the applicant and reviewed by the FR CA. Any comments made by the FR CA, together with our assessment of any new data submitted with the product application, have been added to each section in the green boxes. The greyed-out sections of the PAR are considered to be irrelevant for this product or have been replaced with eCA information in the green boxes.  The product does not contain substances of concern (See section 3.6. Confidential annex); therefore, the assessment of the product DX3 gel is based on the active substance, Imidacloprid.  The emissions assessment has been based on the product containing 0.02 % Imidacloprid. However, it was pointed out by the applicant that this refers to pure a.i. It is more correct to make the emissions assessment on the percentage technical material (as that is what has been used to determine PNEC values), so considering typical batch of imidacloprid of 98 % w/w this would lead to a content of 0.02 %/ 0.98 = 0.0204 % (w/w). This increase would not significantly affect the PEC/PNEC ratios calculated or the overall decision on the acceptability of this product. |

#### Effects assessment on the environment

***Information relating to the ecotoxicity of the biocidal product which is sufficient to enable a decision to be made concerning the classification of the product is required***

Regarding ecotoxicological properties, the formulation is toxic to aquatic organisms with long-lasting adverse effects in the aquatic environment. The proposed classification/labelling of the biocidal product according to GHS is Aquatic Chronic 2, and the hazard statement H411.

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Infobox 2 - FR CA position:   |  |  | | --- | --- | | Classification for the environment of the Active Substance Imidacloprid | | | Value/conclusion | **Very toxic to aquatic life – H400 with M-factor = 100**  **Very toxic to aquatic life with long-lasting effects – H410 with M-factor = 1000** |  |  |  | | --- | --- | | Classification for the environment of the Product DX3 gel | | | Value/conclusion | **Aquatic Chronic Cat 2; H411** | |

***Further Ecotoxicological studies***

Active substances end-points where used to perform environmental risk assessment evaluation. There was no need to perform further ecotoxicological studies.

|  |
| --- |
| Infobox 3 - FR CA position:  In the CAR and assessment report for Imidacloprid, a PNECSTP of 100 mg/L was derived for sewage treatment plants from a standard activated sludge respiration inhibition test with sludge from domestic sewage treatment plant in which a NOEC equal to 5600 mg/L and a EC50 > 10000 mg/L were determined. Nevertheless, the application of the Guidance on the BPR, Volume IV part b slightly modify this value.  In the test submitted on the respiration inhibition of activated sludge also conducted according to OECD 209 (Doc IIIA 7.4.1.4*)*, the NOEC was determined to be 10 000 mg a.s/L. According to the Guidance on the BPR, Volume IV, Part B, Infobox Nr. 7, p. 127 (ECHA, April 2015), if no inhibition is observed for active substances tested at concentrations exceeding their water solubility, the NOEC is now set equal to the water solubility which is subsequently used to derive the PNECstp.  This results in a NOEC of 613 mg/L for the active substance Imidacloprid, since in both tests concentrations higher than the water solubility were used.  With a NOEC value of 613 mg/L derived from the two studies available both conducted according to OECD 209, the **PNECSTP amounts to 61.3 mg/L**.  This would not significantly affect the PEC/PNEC ratios calculated or the overall decision on the acceptability of this product. |

***Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk (ADS)***

Active substances end-points where used to perform environmental risk assessment evaluation. There was no need to perform further ecotoxicological studies.

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | study scientifically not necessary / other information available |
| Justification | Information on further ecotoxicological properties of the biocidal product can be deduced from the respective properties of the a.s. and the co-formulants using the conventional method described under Regulation 1272/2008 (CLP). No effects are expected which cannot be predicted and extrapolated from the endpoints listed in the CAR of the active substance. Furthermore, none of the co-formulants are present in the biocidal product at such a concentration to trigger a classification in accordance with Regulation (EC) No 1272/2008 (CLP). |

***Supervised trials to assess risks to non-target organisms under field conditions***

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | study scientifically not necessary / other information available |
| Justification | Information on further ecotoxicological properties of the biocidal product can be deduced from the respective properties of the a.s. and the co-formulants using the conventional method described under Regulation 1272/2008 (CLP). No effects are expected which cannot be predicted and extrapolated from the endpoints listed in the CAR of the active substance. Furthermore, none of the co-formulants are present in the biocidal product at such a concentration to trigger a classification in accordance with Regulation (EC) No 1272/2008 (CLP). |

***Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk***

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | study scientifically not necessary / other information available |
| Justification | Information on further ecotoxicological properties of the biocidal product can be deduced from the respective properties of the a.s. and the co-formulants using the conventional method described under Regulation 1272/2008 (CLP). No effects are expected which cannot be predicted and extrapolated from the endpoints listed in the CAR of the active substance. Furthermore, none of the co-formulants are present in the biocidal product at such a concentration to trigger a classification in accordance with Regulation (EC) No 1272/2008 (CLP). |

***Secondary ecological effect e.g. when a large proportion of a specific habitat type is treated (ADS)***

No effects are expected which cannot be predicted and extrapolated from the endpoints listed in the CAR of the active substance. All of the non-active ingredients are not significantly toxic to the environment, and most are food grade materials.

***Foreseeable routes of entry into the environment on the basis of the use envisaged***

Biocidal formulation occurs in the EU. All wastes are recycled back into the biocidal product production process or are sent for specialist disposal. There will be no release of the product from the formulation process.

The label instructions indicate that the worst-case treatment regime is application of two droplets of 0.05 g for infestation. This application would be per linear meter and would be as inaccessible (to children, pets) as possible within the treated area.

The Predicted Environmental Concentrations (PECs) for this emission scenario are calculated using EUSES 2.1.2 PT18 insecticide scenario.

The Transitional Guidance on mixture toxicity assessment for biocidal products for the environment requires that possible synergy between components and the active are considered and that PEC/PNEC ratios should be for the mixture. However, this only works if the whole mixture remains together all the way from the source of emission to the relevant environmental compartments. Therefore, the transitional guidance allows for the normal PEC/PNEC approach where separation of the active from the product is likely, as is the case here. There is no indication that any of the components will have a synergistic effect on the active.

Physico-chemical data used in the model was taken from the List of Endpoints in the Assessment Report.

***Further studies on fate and behaviour in the environment (ADS)***

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | study scientifically not necessary / other information available |
| Justification | Information on further ecotoxicological properties of the biocidal product can be deduced from the respective properties of the a.s. and the co-formulants using the conventional method described under Regulation 1272/2008 (CLP). No effects are expected which cannot be predicted and extrapolated from the endpoints listed in the CAR of the active substance. Furthermore, none of the co-formulants are present in the biocidal product at such a concentration to trigger a classification in accordance with Regulation (EC) No 1272/2008 (CLP). |

***Leaching behaviour (ADS)***

No effects are expected which cannot be predicted and extrapolated from the endpoints listed in the CAR of the active substance. All of the non-active ingredients are not significantly toxic to the environment, and most are food grade materials.

***Testing for distribution and dissipation in soil (ADS)***

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | study scientifically not necessary / other information available |
| Justification | Information on further ecotoxicological properties of the biocidal product can be deduced from the respective properties of the a.s. and the co-formulants using the conventional method described under Regulation 1272/2008 (CLP). No effects are expected which cannot be predicted and extrapolated from the endpoints listed in the CAR of the active substance. Furthermore, none of the co-formulants are present in the biocidal product at such a concentration to trigger a classification in accordance with Regulation (EC) No 1272/2008 (CLP). |

***Testing for distribution and dissipation in water and sediment (ADS)***

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | study scientifically not necessary / other information available |
| Justification | Information on further ecotoxicological properties of the biocidal product can be deduced from the respective properties of the a.s. and the co-formulants using the conventional method described under Regulation 1272/2008 (CLP). No effects are expected which cannot be predicted and extrapolated from the endpoints listed in the CAR of the active substance. Furthermore, none of the co-formulants are present in the biocidal product at such a concentration to trigger a classification in accordance with Regulation (EC) No 1272/2008 (CLP). |

***Testing for distribution and dissipation in air (ADS)***

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | study scientifically not necessary / other information available |
| Justification | Information on further ecotoxicological properties of the biocidal product can be deduced from the respective properties of the a.s. and the co-formulants using the conventional method described under Regulation 1272/2008 (CLP). No effects are expected which cannot be predicted and extrapolated from the endpoints listed in the CAR of the active substance. Furthermore, none of the co-formulants are present in the biocidal product at such a concentration to trigger a classification in accordance with Regulation (EC) No 1272/2008 (CLP). |

***If the biocidal product is to be sprayed near to surface waters then an overspray study may be required to assess risks to aquatic organisms or plants under field conditions (ADS)***

**Acute aquatic toxicity**

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | study scientifically not necessary / other information available |
| Justification | The biocidal product is a gel bait applied in confined areas. A risk assessment for spray application is therefore deemed not appropriate. |

**Chronic aquatic toxicity**

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | study scientifically not necessary / other information available |
| Justification | The biocidal product is a gel bait applied in confined areas. A risk assessment for spray application is therefore deemed not appropriate. |

**Measured aquatic bioconcentration**

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | study scientifically not necessary / other information available |
| Justification | The biocidal product is a gel bait applied in confined areas. A risk assessment for spray application is therefore deemed not appropriate. |

***If the biocidal product is to be sprayed outside or if potential for large scale formation of dust is given then data on overspray behaviour may be required to assess risks to bees and non-target arthropods under field conditions (ADS)***

The biocidal product is a gel bait applied in confined areas. A risk assessment for spray application is therefore deemed not appropriate. The product DX3 GEL (in gel form) contains the active substance Imidacloprid known to be toxic to bees (LD50 oral = 0.0037µg/bee and LD50 contact = 0.081µg/bee) and therefore a risk for bees cannot be excluded. The proposed way of application of the product is local and spot-wise (small-scale application) directly into/onto or around ant nests/path. Because of the limited area, only single forager bees might be affected, but not a whole bee colony. Consequently, on population level, no significant risk is anticipated to honey bees. This conclusion is analogously applicable to other beneficial arthropods. However, considering that the risk cannot be excluded, it can be prevented adopting some Risk Mitigation Measures. To this purpose, DX3 GEL SPC and label report that if applied outdoor as loose, gel spots should be covered, for example with a flower pot in order to minimize potential exposure of the gel to bees or other non-target insects. Moreover, in label instruction it is stated that gel can be applied in containers. This way of application may further contribute to limit the toxicity of the product toward bees and non-target insects.

Conclusion: The exposure to bees and other beneficials can be considered negligible due to the small-scale application and due to the RMMs proposed.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Infobox 4- FR CA position:  PNEC values proposed in the Assessment Report of Imidacloprid (rev. 07/2015).   |  |  | | --- | --- | | Summary table on PNEC for Imidacloprid | | | Environmental compartment | PNEC value | | STP | 61.3 mg.L-1 | | Surface water | 4.80E-06 mg.L-1 | | Freshwater sediment (EPM) | 2.60E-05 mg.kgwwt-1 | | Soil (initial) | 1.58E-02 mg.kgwwt-1 | | PNEC oral bird | 4.20 mg.kg-1 food | | PNEC oral small mammal | 8.33 mg.kg-1 food |   **Bees assessment:**  The product DX3 GEL (in gel form) contains the active substance Imidacloprid known to be toxic to bees and therefore a risk for bees cannot be excluded (cf Infobox N°18) |

#### Exposure assessment

General information

|  |  |
| --- | --- |
| Assessed PT | *PT18* |
| Assessed scenarios | *Scenario 1: Professional use indoor of domestic and civil buildings: worst case in comparison to non-professional use (only domestic application)*  *Scenario 2: Non-professional bait box application indoor*  *Scenario 3:Professional use around buildings, spot application, worst case in comparison to non-professional use*  *Scenario 4: Outdoor application of gel bait on nest around buildings (according to TAB: terrace scenario)*  *Scenario 5: Outdoor application of gel bait on nest on bare soil*  *Scenario 6: Bait box application on terrace*  *Scenario 7: Outdoor application of bait box on nest on bare soil* |
| ESD(s) used | *Emission Scenario Document for Product Type 18: EMISSION SCENARIO DOCUMENT FOR INSECTICIDES, ACARICIDES AND PRODUCTS TO CONTROL OTHER ARTHROPODS FOR HOUSEHOLD AND PROFESSIONAL USES* |
| Approach | *Scenario 1: ESD model, EUSES 2.1: indoor gel application;*  *Scenario 2: ESD model, EUSES 2.1: indoor gel application*  *Scenario 3: ESD model, EUSES 2.1: Outdoor spot application*  *Scenario 4: ESD model, EUSES 2.1: Outdoor spot application*  *Scenario 5: ESD model, EUSES 2.1: Outdoor spot application*  *Scenario 6: ESD model, EUSES 2.1: Outdoor spot application*  *Scenario 7: ESD model, EUSES 2.1: Outdoor spot application* |
| Distribution in the environment | *Calculated based on ESD model, EUSES 2.1* |
| Groundwater simulation | *NO – calculated according to eq. 67 Guidance on the Biocidal Products Regulation, Volume IV Environment - Assessment and Evaluation (Parts B + C)* |
| Confidential Annexes | *YES: All data and risk assessment evaluation is to be intended as confidential both along this document and in its Annexes.* |
| Life cycle steps assessed | *Scenario n: All the scenarios:*  *Production: No*  *Formulation No*  *Use: Yes*  *Service life: Yes* |
| Remarks | */* |

***Emission estimation***

**Scenario [1]**

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | |
| **Input** | **Value** | **Unit** | **Remarks** |
| Scenario: *Professional use indoor of domestic and civil buildings* | | | |
| Application rate of biocidal product | 0.05 | *g/point* | 3 droplet/m2 for high infestation |
| Concentration of active substance in the product | 0.02 | *%* |  |
| Number of gel point per area | 8 | Point/m2 | Worst-case considering that the intended application is per linear meter according to label instructions |
| Area treated: Household | 130 | m2 |  |
| Area treated: Larger buildings | 609 | m2 |  |
| Cleaning efficiency | 3 | % | Default |
| Number of houses per STP\* | 4000 | - | Default |
| Number of larger buildings per STP | 300\*\* | - | Default |
| Simultaneity factor | 5.5 | % | Default as worst-case |

\* as stated in TAB for targeted application areas in houses and larger buildings

\*\* as stated in TAB for commercial buildings. Note that the same MOTA also states that *no separate assessment for hospitals will be included* and that the number of commercial buildings of 300 is considered to ***include also hospitals***. Therefore, the assessment for larger buildings in this risk assessment also covers use in hospitals.

Calculations for Scenario [*1*]

| **Resulting local emission to relevant environmental compartments** | | |
| --- | --- | --- |
| **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** |
| STP | 9.31E-05 |  |

|  |
| --- |
| Infobox 5 – FR CA position:  The FR CA has recalculated the emission to the STP compartment based on a refined application area and a more realistic cleaning efficiency.  **Application rate of the biocidal product and number of gel point per area:**  According to the intended uses, the application rate is of 2 droplets per linear meter, corresponding to an application rate of **8 droplets per m2**.  **Treated areas**:  With regard to the indoor area to be treated with the product, the applicant used a value of 130 m2 for a house and 609 m2 for large buildings. These values represent the total area inside each type of building and are assumed as worst-case scenarios by the applicant. Nevertheless, it is considered that the DX3 gel is intended to be used in cracks and crevices or along a perimeter indoor. A ‘barrier’ scenario covers a total surface of 20 m2 for a domestic house and 93m2 for a large building seems therefore more realistic. These values for barrier treatment were corrected for the wet cleaned zone. The area values selected were 5.9 m2 for a private house and 27 m2 for large buildings.  **Cleaning efficiency**:  A cleaning efficiency of 25% instead of 3 % proposed by the applicant has then been adopted according to the ESD as a protective scenario (gel for surface in the ESD) assuming the product applied along the ant runways could be washed away and reach the STP by unexpected flooding or via accidental spillages.  Assuming these new input parameters, and taking into account the a.s. technical value, **ElocalSTP=3.56E-05 kg.d-1** |

**Scenario [2]**

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | |
| **Input** | **Value** | **Unit** | **Remarks** |
| Scenario: *bait box application indoor* | | | |
| Application rate of biocidal product | 1 | *Bait box* | 4grams/bait box as worst case |
| Concentration of active substance in the product | 0.02 | % |  |
| Area treated: Household | 38.5 | m2 | TAB August 2017 |
| Area treated: Larger Buildings | 180 | m2 | TAB August 2017 |
| Fraction emitted to treated surfaces during application | 20 | % | TAB August 2017 |
| Cleaning efficiency | 0 | % | Default as indicated in ESD for PT18 for indoor treatment (page34) |
| Washable or disposable applicators | Disposable |  | Bait box are not refillable, item has to be disposed in solid waste and in compliance with local regulations |

\* as stated in TAB for targeted application areas in houses and larger buildings

\*\* as stated in TAB for commercial buildings. Note that the same MOTA also states that *no separate assessment for hospitals will be included* and that the number of commercial buildings of 300 is considered to ***include also hospitals***. Therefore, the assessment for larger buildings in this risk assessment also covers use in hospitals.

Calculations for Scenario [*2*]

| **Resulting local emission to relevant environmental compartments** | | |
| --- | --- | --- |
| **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** |
| Freshwater | 0 | Emissions of the active substance to the environment for indoor treatment are excluded due to the application form (bait box). |
| Freshwater sediment | 0 | Emissions of the active substance to the environment for indoor treatment are excluded due to the application form (bait box). |
| Seawater | 0 | Emissions of the active substance to the environment for indoor treatment are excluded due to the application form (bait box). |
| Seawater sediment | 0 | Emissions of the active substance to the environment for indoor treatment are excluded due to the application form (bait box). |
| STP | 0 | Emissions of the active substance to the environment for indoor treatment are excluded due to the application form (bait box). |
| Air | 0 | Emissions of the active substance to the environment for indoor treatment are excluded due to the application form (bait box). |
| Soil | 0 | Emissions of the active substance to the environment for indoor treatment are excluded due to the application form (bait box). |
| Groundwater | 0 | Emissions of the active substance to the environment for indoor treatment are excluded due to the application form (bait box). |

Emissions of the active substance to the environment for indoor treatment are excluded due to the application form (bait box). The ESD for PT18 (OECD, 2008) states (at page 34) that “for these products, emissions to the environment during the treatment are negligible. The only possible emission is when the box is eliminated to waste during indoor uses”. According to the waste disposal instructions indicated in product label and in compliance to national legislation and municipal capabilities, the disposal of the empty box should not pose a risk for the environment. Therefore, the assessment of the environmental risk from indoor use of the bait box containing Imidacloprid is irrelevant.

|  |
| --- |
| Infobox 6 – FR CA position:  The FR CA agrees with the applicant argumentation: no emission of the a.s. to the environment is expected for bait boxes indoor treatment. |

**Scenario [3]**

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | |
| **Input** | **Value** | **Unit** | **Remarks** |
| Scenario: *Professional use around buildings, spot application* | | | |
| Application rate of biocidal product | 0.05 | *g/spot* |  |
| Concentration of active substance in the product | 0.02 | *%* |  |
| Number of total spot | 100 | - | 100 spot for domestic buildings + 100 spots for larger buildings. A proper emission scenario for the evaluation of a perimeter treatment is lacking. As worst-case it is assumed that a Professional users will apply 100 spots both in domestic and larger buildings. The scenario represents clearly a worst case situation considering that the total amount of product (10g) do not reflect the real use and application of the product. The scenarios is therefore extremely over-conservative. |
| Area exposed | 0.25 | m2 | Default |
| Volume area | 0.125 | m3 | Default |
| Number of houses per STP\* | 2500 | - | Default |
| Number of larger buildings per STP | 300\*\* | - | Default |
| Simultaneity factor | 3 | % | Default as worst-case |

\* as stated in TAB for targeted application areas in houses and larger buildings

\*\* as stated in TAB for commercial buildings. Note that the same MOTA also states that *no separate assessment for hospitals will be included* and that the number of commercial buildings of 300 is considered to ***include also hospitals***. Therefore, the assessment for larger buildings in this risk assessment also covers use in hospitals.

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| Infobox 7 – FR CA position:  The spot number for large buildings proposed by the applicant is not validated by FR CA: assuming that the perimeter of a large building is 100m long and that the number of spots per linear meter is 2, this results in **200** spots for ‘large building perimeter’ scenario.  Apart from this specific point, we agree with the input parameters taken by the applicant.  For your information, the emission assessment is based on an unsheltered area, assuming that the fraction released to the environment is **90%** (default value ESD PT18 for gel spot). |

Calculations for Scenario [*3*]

In case of outdoor applications in areas not directly connected to STP, emissions to the bare soil following weathering may occur. Then, direct exposure of the soil compartment is also assessed.

The soil area around a building is calculated considering a 0.5 m soil strip adjacent to a typical private house of 17.5 meters long and 7.5 meters wide, and a larger building of 609m2 corresponding to a square of 24.678 m wide. The surface of the four soil corners of 0.5 m side length is added. Hence, the soil area exposed around a private house is:

AREAexposed = [2\*(0.5\*7.5)] + [2\*(0.5\*17.5)] + [4\*(0.5\*0.5)] = 26 m2 (‘House perimeter’ scenario)

The soil area exposed around a larger building is:

AREAexposed = [4\*24.678\*0.5] + [4\*0.5\*0.5] = 50.4 m2 (‘Larger building perimeter’ scenario).

| **Resulting local emission to relevant environmental compartments** | | |
| --- | --- | --- |
| **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** |
| STP | 7.65E-05 |  |
| Soil (bare soil – direct release) | 1.8E-06 |  |

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| Infobox 8 – FR CA position:  The Elocal values have been revised taking into account the technical value of Imidacloprid (0.0204%), and the correct number of drops for large buildings.  Moreover, we would like to clarify that the Elocalsoil(bare soil-direct release) presented by the applicant is the result gathered for larger buildings (worst-case). In fact, as the receiving soil volume is proportional to the perimeter length, the house and large buildings scenarios will be equivalent in term of PEC values.   | **Resulting local emission to relevant environmental compartments – Scenario 3 (outdoor; gel; perimeter)** | | | | --- | --- | --- | | **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** | | STP | 8.54E-05 | (houses + large buildings) | | Soil (bare soil – direct release) | 9.18E-07 | Larger building | |

**Scenario [4]**

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | |
| **Input** | **Value** | **Unit** | **Remarks** |
| Scenario: *Outdoor application of gel bait on nest around buildings (according to TAB: terrace scenario)* | | | |
| Application rate of biocidal product | 0.05 | *g/spot* |  |
| Concentration of active substance in the product | 0.02 | *%* |  |
| Number of total spot | 30 | - | 30 spot for domestic buildings + 30 spots for larger buildings. |
| Number of nests treated | 4 | - | For the scenario 4 it is assumed that 4 nests are treated applying 1.5 g for each nest around the perimeter of the house/building. Therefore 30spots of 0.05 g x 4 nests are considered for house and buildings (=120 spots for house and 120 spots for building) applying the terrace scenario. |
| Area exposed | 8.5 | m2 | According to the TAB (terrace scenario) |
| Volume area | 4.25 | m3 | Default |
| Number of houses per STP\* | 2500 | - | Default |
| Number of larger buildings per STP | 300\*\* | - | Default |
| Simultaneity factor | 3 | % | Default |

\* as stated in TAB for targeted application areas in houses and larger buildings

\*\* as stated in TAB for commercial buildings. Note that the same MOTA also states that *no separate assessment for hospitals will be included* and that the number of commercial buildings of 300 is considered to ***include also hospitals***. Therefore, the assessment for larger buildings in this risk assessment also covers use in hospitals.

|  |
| --- |
| Infobox 9- FR CA position:  For information, emissions from the treated surfaces are calculated considering, that the fraction released to the environment following wash-off by rainfall is 90% (default value ESD PT18 for gel spot). |

Calculations for Scenario [*4*]

In case of outdoor applications in areas not directly connected to STP, emissions to the bare soil may occur. Then, direct exposure of the soil compartment is also assessed: the soil area around the terrace for a house and a building is set at 8.5m2.

| **Resulting local emission to relevant environmental compartments** | | |
| --- | --- | --- |
| **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** |
| STP | 9.07E-05 |  |
| Soil (bare soil – direct release) | 2.16E-06 |  |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Infobox 10 - FR CA position:  FR CA agrees with the resulting local emission to the STP compartment.  Nevertheless, we would like to emphasize that the Elocalsoil(bare soil – direct release) presented by the applicant is the result gathered for larger buildings **and** private buildings. This is not relevant to add these values due to the direct release in the bare soil.  Taking into account the a.s. technical value, here are the results presented by the FR CA:   | **Resulting local emission to relevant environmental compartments – Scenario 4 (outdoor; gel ; terrace)** | | | | --- | --- | --- | | **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** | | STP | 9.25E-05 |  | | Soil (bare soil –direct release) | 1.10E-06 | Larger buiding **or** house | |

**Scenario [5]**

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | |
| **Input** | **Value** | **Unit** | **Remarks** |
| Scenario: *Outdoor application of gel bait on nest on bare soil* | | | |
| Application rate of biocidal product | 0.05 | *g/spot* |  |
| Concentration of active substance in the product | 0.02 | *%* |  |
| Number of total spot | 30 | - | Assuming to treat the area of 1m2 applying a total amount of 1.5 g of product as reported in label instructions |
| Area exposed | 1 | m2 | According to a mean area of an ant nest (i.e. nest treated for field efficacy assessment of DX3 GEL) |
| Volume area | 0.5 | m3 | Default |
| Number of houses per STP\* | 2500 | - | Default |
| Number of larger buildings per STP | 300\*\* | - | Default |
| Simultaneity factor | 3 | % | Default |

\* as stated in TAB for targeted application areas in houses and larger buildings

\*\* as stated in TAB for commercial buildings. Note that the same MOTA also states that *no separate assessment for hospitals will be included* and that the number of commercial buildings of 300 is considered to ***include also hospitals***. Therefore, the assessment for larger buildings in this risk assessment also covers use in hospitals.

Calculations for Scenario [*5*]

Considering the route of exposure for such application, emission to STP, freshwater and sediment are considered to be negligible.

Indeed the principal interested compartment is the bare soil and indirectly groundwater.

| **Resulting local emission to relevant environmental compartments** | | |
| --- | --- | --- |
| **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** |
| Soil | 3.53E-04 |  |
| Groundwater |  |  |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Infobox 11 – FR CA position:  The applicant presents the result of Csoil(house or building) , considering a direct application of the product on bare soil.  In the ESD, the default value of the gel fraction released in the environment is Fspot,gel=0.9, considering that gels are not applied on porous surface. As the product is applied on a bare soil in this scenario, the applicant changed this default value, admitting that all the product is released to the environment (Fspot,gel =1).  Here are the related results presented by FR CA of the Elocalsoil (bare soil–direct release), with the a.s. technical value:   | **Resulting local emission to relevant environmental compartments – Scenario 5 (outdoor; gel; bare soil; nest)** | | | | --- | --- | --- | | **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** | | Soil (bare soil – direct release): | 3.06E-07 | large building **or** houses | |

**Scenario [6]**

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | |
| **Input** | **Value** | **Unit** | **Remarks** |
| Scenario: *Bait box application on terrace* | | | |
| Application rate of biocidal product | 4 | *g* | Worst-case amount of product within a bait box |
| Concentration of active substance in the product | 0.02 | *%* |  |
| Number of total spot | 4 | 4 for houses and 4 for buildings | Quantity to cover a terrace application by a professional treating both domestic and larger buildings. |
| Fraction of emission to soil | 0.2 | - |  |
| Area exposed | 8.5 | m2 | Default area for terrace scenario according to TAB 2017 |
| Volume area | 4.25 | m3 | Default |
| Number of houses per STP\* | 2500 | - | Default |
| Number of larger buildings per STP | 300\*\* | - | Default |
| Simultaneity factor | 3 | % | Default as worst-case |

\* as stated in TAB for targeted application areas in houses and larger buildings

\*\* as stated in TAB for commercial buildings. Note that the same MOTA also states that *no separate assessment for hospitals will be included* and that the number of commercial buildings of 300 is considered to ***include also hospitals***. Therefore, the assessment for larger buildings in this risk assessment also covers use in hospitals.

Calculations for Scenario [*6*]

In case of outdoor applications, even in case of applications with bait boxes, in areas not directly connected to STP, emissions to the bare soil may occur. Then, direct exposure of the soil compartment is also assessed: the soil area around the terrace for a house and a building is set at 8.5m2.

| **Resulting local emission to relevant environmental compartments** | | |
| --- | --- | --- |
| **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** |
| STP | 5.38E-05 |  |
| Soil | 1.77E-04 |  |
| Groundwater |  |  |

|  |  |  |  |  |  |  |  |  |  |  |  |  |
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| Infobox 12 – FR CA position :  FR CA agrees with the resulting local emission for the STP compartment. Nevertheless, we would like to emphasize that the Elocalsoil presented by the applicant is a sum of each Csoil (large buildings **and** household).  FR CA presents the results of the Elocalsoil , with the a.s. technical value:   | **Resulting local emission to relevant environmental compartments (outdoor; box; terrace; nest)** | | | | --- | --- | --- | | **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** | | STP | 5.48E-05 |  | | Soil (bare soil – direct release): | 6.53E-07 | large building **or** houses | |

**Scenario [7]**

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | |
| **Input** | **Value** | **Unit** | **Remarks** |
| Scenario: *Outdoor application of bait box on nest on bare soil* | | | |
| Application rate of biocidal product | 4 | *g* | Worst-case amount of product within a bait box |
| Concentration of active substance in the product | 0.02 | *%* |  |
| Number of total spot | 1 | - | 1 nest treated |
| Fraction of emission to soil | 0.2 | - |  |
| Area exposed | 1 | m2 | Default area for terrace scenario |
| Volume area | 0.5 | m3 | Default |
| Number of houses per STP\* | 2500 | - | Default |
| Number of larger buildings per STP | 300\*\* | - | Default |
| Simultaneity factor | 3 | % | Default as worst-case |

\* as stated in TAB for targeted application areas in houses and larger buildings

\*\* as stated in TAB for commercial buildings. Note that the same MOTA also states that *no separate assessment for hospitals will be included* and that the number of commercial buildings of 300 is considered to ***include also hospitals***. Therefore, the assessment for larger buildings in this risk assessment also covers use in hospitals.

Calculations for Scenario [*7*]

This scenario allows a further refinement of the application against ants in proximity of nests, by applying bait boxes near nest entrances. Bait box are sealed and no direct emissions to relevant environmental compartments are expected to occur. The very few amount of bait that ants may transport to the nest before dying should lead to negligible emissions.

| **Resulting local emission to relevant environmental compartments** | | |
| --- | --- | --- |
| **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** |
| Soil | 1.88E-04 |  |
| Groundwater |  |  |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Infobox 13 – FR CA position :  We would like to emphasize that the Elocalsoil presented by the applicant is a sum of each Csoil (large buildings **and** household).  FR CA presents the results of the Elocalsoil , with the a.s. technical value:   | **Resulting local emission to relevant environmental compartments (outdoor; box; bare soil; nest)** | | | | --- | --- | --- | | **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** | | Soil (bare soil – direct release ): | 1.63E-07 | large building **or** house | |

***Fate and distribution in exposed environmental compartments***

| **Identification of relevant receiving compartments based on the exposure pathway** | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Fresh-water | Freshwater sediment | Sea-water | Seawater sediment | STP | Air | Soil | Ground-water | Other |
| Scenario 1 | Yes (indirect) | Yes (indirect) | Not relevant | Not relevant | Yes (direct) | no | Yes (indirect) | Yes (indirect) | Not relevant |
| Scenario 2 | Negligible | Negligible | Negligible | Negligible | Negligible | Negligible | Negligible | Negligible | Negligible |
| Scenario 3 | Yes (indirect) | Yes (indirect) | Not relevant | Not relevant | Yes (direct) | no | Yes (indirect) | Yes (indirect) | Not relevant |
| Scenario 4 | Yes (indirect) | Yes (indirect) | Not relevant | Not relevant | Yes (direct) | no | Yes (indirect) | Yes (indirect) | Not relevant |
| Scenario 5 | Negligible | Negligible | Negligible | Negligible | Negligible | Negligible | Yes | Negligible | Negligible |
| Scenario 6 | Yes (indirect) | Yes (indirect) | Not relevant | Not relevant | Yes (direct) | no | Yes (indirect) | Yes (indirect) | Not relevant |
| Scenario 7 | Negligible | Negligible | Negligible | Negligible | Negligible | Negligible | Yes | Negligible | Negligible |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Infobox 14 – FR CA position:  FR CA would like to give more precisions on the fate and distribution in exposed environmental compartments:   | Compartment  Scenario N° | Fresh-water | Freshwater sediment | Sea-water | Seawater sediment | STP | Soil | Ground-water | | --- | --- | --- | --- | --- | --- | --- | --- | | Indoor scenarios | | | | | | | | | **1** - gel | Yes (indirect) | Yes (indirect) | Not relevant | Not relevant | Yes (direct) | Yes (indirect) | Yes (indirect) | | **2** - box | Negligible | Negligible | Not relevant | Not relevant | Negligible | Negligible | Negligible | | Outdoor scenarios | | | | | | | | | **3** - gel; perimeter | Yes (indirect) | Yes (indirect) | Not relevant | Not relevant | Yes (direct) | Yes (direct + indirect) | Yes (direct + indirect) | | **4** - gel; terrace; nest | Yes (indirect) | Yes (indirect) | Not relevant | Not relevant | Yes (direct) | Yes (direct + indirect) | Yes (direct + indirect) | | **5**- gel; bare soil; nest | Negligible | Negligible | Not relevant | Not relevant | Negligible | Yes (direct) | Yes (direct) | | **6**- box; terrace; nest | Yes (indirect) | Yes (indirect) | Not relevant | Not relevant | Yes (direct) | Yes (direct + indirect) | Yes (direct + indirect) | | **7-** box; bare soil; nest | Negligible | Negligible | Not relevant | Not relevant | Negligible | Yes (direct) | Yes (direct) | |

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters (only set values) for calculating the fate and distribution in the environment** | | | |
| Input | Value | Unit | Remarks |
| Molecular weight | 255.7 | g/mol-1 |  |
| Melting point | 144 | °C |  |
| Vapour pressure (at 20°C) | 4E-10 | Pa |  |
| Water solubility (at 20°C) | 613 | mg/l |  |
| Log Octanol/water partition coefficient | 0.57 | Log 10 |  |
| Organic carbon/water partition coefficient (Koc) | 230 | l/kg |  |
| Henry’s Law Constant (at 25°C) | 3.5E-10 | Pa/m3/mol |  |
| Biodegradability | *Not biodegradable* |  |  |
| Rate constant for STP | 0 | h-1 |  |
| DT50 for biodegradation in surface water | 185.4 | d (at 12ºC) |  |
| DT50 for photolysis in surface water | 135.1 | d (at 12°C) |  |
| DT50 for biodegradation in aerated sediment | 184.5 | d (at 12ºC) |  |

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| Infobox 15 – FR CA position:  FR CA do not agree with all the input parameters presented by the applicant. Please see the table below for the revised inputs:   |  |  |  |  | | --- | --- | --- | --- | | **Input parameters (only set values) for calculating the fate and distribution in the environment** | | | | | Input | Value | Unit | Remarks | | Ready biodegradability | NO |  |  | | DT50 for biodegradation total system water sediment | 185.4 | d (at 12ºC) |  | | DT50 biodegradation in soil | 135.1 | d (at 12°C) |  | | Ksoil arable land (depth 20 cm) | 5.47E-03 | d-1 (at 12°C) |  | | BCFfish , measured | 6.10E-01 | L.kg-1wwt |  | | BCFearthworm , calculated | 8.80E-01 | L.kg-1wwt |  | | BMFfish | 1.00 | [-] |  | |

|  |  |  |
| --- | --- | --- |
| **Calculated fate and distribution in the STP *[if STP is a relevant compartment]*** | | |
| Compartment | Percentage [%] | Remarks |
| Scenario 1 – 3 – 4 – 6 -7 |
| Air | 3.37E-10 |  |
| Water | 97.2 |  |
| Sludge | 2.79 |  |
| Degraded in STP | 0 |  |

|  |
| --- |
| Infobox 16 – FR CA position:  FR CA agree with the results presented by the applicant, using SimpleTreat 4.0. Please note that STP is a relevant compartment only for Scenarios 1, 3, 4 and 6. The scenarios 5 and 7 are assessed for the use on bare soil, leading only to a direct emission to the soil compartment. The scenario 2 leads to zero emission to the environment. |

***Calculated PEC values***

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Summary table on calculated PEC values** | | | | | | | | | |
|  | **PECSTP** | **PECwater** | **PECsed** | **PECseawater** | **PECseased** | **PECsoil** | **PECGW1** | **PECair** |
| [mg/ml] | [mg/l] | [mg/kgwwt] | [mg/l] | [mg/kgwwt] | [mg/ kgwwt] | [mg/l] | [mg/m3] |
| Scenario 1 | 4.51E-05 | 4.51E-06 | 2.6E-05 | / | / | 5.14E-06 | 8.5E-07 | 2.38E-22 |
| Scenario 2 | 0 | 0 | 0 | / | / | 0 | 0 | 0 |
| Scenario 3 | 3.67E-05 | 3.67E-06 | 2.12E-05 | / | / | 1.52E-04 | 2.48E-05 | 1.94E-22 |
| Bare soil at site of application: 6.19E-05 | at site of application: 1.48E-05 |
| Scenario 4 | 4.41E-05 | 4.41E-06 | 2.55E-05 | / | / | 3.19E-04 | 5.27E-05 | 2.32E-22 |
| Bare soil at site of application: 2.99E-04 | at site of application: 7.16E-05 |
| Scenario 5 | 0 | 0 | 0 | / | / | 3.53E-04 | 6.22E-05 | 0 |
| Scenario 6 | 2.61E-05 | 2.61E-06 | 1.51E-05 | / | / | 1.07E-04 | 1.77E-05 | 6.9E-23 |
| Bare soil at site of application: 1.77E-04 | at site of application: 4.24E-05 |
| Scenario 7 | 0 | 0 | 0 | / | / | 1.88E-04 | 3.25E-05 | 0 |
| 1 If the PECGW was calculated by using a simulation tool (e.g. one of the FOCUS models), please provide the results for the different simulated scenarios in a separate table. | | | | | | | | | |

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| Infobox 17 – FR CA position :  FR CA does not agree with some PEC. Revised results are summarised below:   |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | | **Summary table on calculated PEC values** | | | | | | | | | **Scenario N°** | **Primary receiving compartment** | **PECSTP** | **PECwater** | **PECsed** | | **PECsoil initial** | **PECGW1** | | [mg/L] | [mg/l] | [mg/kgwwt] | | [mg/kgwwt] | [mg/l] | | **Indoor scenarios** | | | | | | | | | **1** - gel | STP | 1.73E-05 | 1.73E-06 | 9.99E-05 | | 2.14E-06 | 5.12E  -07 | | **2**- box | Not relevant | Not relevant | Not relevant | Not relevant | | Not relevant | Not relevant | | **Outdoor scenarios** | | | | | | | | | **3** -gel; perimeter | STP | 4.15E-05 | 4.15E-06 | | 2.40E-05 | 5.13E-06 | 1.23E-06 | | Soil | Not relevant | Not relevant | | Not relevant | 4.15E-05 | 9.95E-06 | | **4** -gel; terrace; nest | STP | 4.50E-05 | 4.50E-06 | 2.60E-05 | | 5.56E-06 | 1.33E-06 | | Soil | Not relevant | Not relevant | Not relevant | | 1.52E-04 | 3.65E-05 | | **5**- gel; bare soil; nest | Soil | Not relevant | Not relevant | Not relevant | | 3.60E-04 | 8.62E-05 | | **6**- box; terrace; nest | STP | 2.66E-05 | 2.66E-06 | 1.54E-05 | | 3.30E-06 | 7.89E-07 | | Soil | Not relevant | Not relevant | Not relevant | | 9.04E-05 | 2.16E-05 | | **7-** box; bare soil; nest | Soil | Not relevant | Not relevant | Not relevant | | 1.92E-04 | 4.60E-05 | | 1 *Calculated as: PECsoil ini \* RHOsoil/ (ksoil-water \* 1000); eq67 Guidance on the Biocidal Products Regulation, Volume IV Environment - Assessment and Evaluation (Parts B + C)* | | | | | | | | |

***Primary and secondary poisoning***

Justification for non-relevance:

1. Log Kow = 0.57 leading to a calculated BCF of 0.61 for fish (ref: Assessment Report)

2. No accumulation was observed in a toxicokinetic study in rat (ref: Assessment Report)

According to the new ECHA guidance on environmental assessment (v.1, volume IV, part B), if log Kow is less than 3 and there are other mitigating properties (which in this case is the lack of observed accumulation in the toxicokinetic study in rat) then there is no potential for bioaccumulation.

In addition, the Assessment Report also states no potential for accumulation of Imidacloprid.

However, according to EUSES calculation, considering the spot application of gel outdoor as the most representative application to estimate secondary exposure, concentration in fish for secondary poisoning (freshwater) is 7.11E-09 mg/kg wet weight and concentration in earthworms from agricultural soil is 4.22E-07 mg/kg.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Infobox 18 – FR CA position :  **Bees assessment:**  The product DX3 GEL (in gel form) contains the active substance Imidacloprid known to be toxic to bees (LD50 oral = 0.0037 µg/bee and LD50 contact = 0.081 µg/bee) and therefore a risk for bees cannot be excluded.  Furthermore, DX3 gel is formulated with 70% of sugar. Considering the concentration of imidacloprid in DX3 gel (0.0204% w/w), volumes of product necessary to reach LD50 oral  and the LD50 contact are respectively 0.185 µL and 0.405 µL per bee. Therefore, exposure of a honeybee at and above the LD50 is very likely.  For these reasons, FR CA suggests that when used outdoors, the product must be used in pre-filled bait boxes to protect from non-target organisms. When this is not practically possible, crack and crevice applications are also permitted in order to minimize access from non-target organisms and rainfall. With respect to the condition of outdoor uses, honeybee exposure can be considered as negligible. The following RMM has been added by the FR CA:   * “For outdoor use, apply this biocidal product in bait boxes or in cracks and crevices only or directly to ant nests. Protect from bees and the weather by covering, for example with a flowerpot or a tile (ensuring that the ants still get access to the bait)”.   **Secondary poisoning:**  The applicant choose to conduct a qualitative and quantitative exposure assessment in order to justify the non-relevance of this assessment.  FR CA does not find the same value, to clarify that point PEC values for secondary poisoning are summarised below:   |  |  |  |  | | --- | --- | --- | --- | | **Summary table on calculated PEC values** | | | | | **Scenario N°** | **Receiving compartment** | **PECoral predator FISH** | **PECoral predator EARTHWORM (agricultural soil)** | | [mg/kgwet fish] | [mg/kgwet earthworm] | | **Indoor scenarios** | | | | | **1** gel | STP | 5.27E-07 | 3.34E-07 | | **2**- box | Not relevant | Not relevant | Not relevant | | **Outdoor** | | | | | **3** -gel; perimeter | STP | 1.27E-06 | 8.01E-07 | | Soil | Not relevant | 6.48E-06 | | **4** -gel; terrace; nest | STP | 1.37E-06 | 8.68E-07 | | Soil | Not relevant | 2.38E-05 | | **5**- gel; bare soil; nest | Soil | Not relevant | 5.62E-05 | | **6**- box; terrace; nest | STP | 8.13E-07 | 5.14E-07 | | Soil | Not relevant | 1.41E-05 | | **7-** box; bare soil; nest | Soil | Not relevant | 3.00E-05 | |

***Metabolites***

According to the new ECHA guidance on environmental assessment (v.1, volume IV, part B) in general, an environmental risk assessment for the relevant compartments needs to be performed for all major metabolites.

In ECHA guidance document volume IV A, part 1 it is stated that *major metabolites are* *metabolites formed ≥ 10% on a molar basis, of the active substance in any relevant environmental compartment or appear at two consecutive sampling points at amounts ≥ 5% on a molar basis, or if at the end of the study the maximum of formation is not yet reached but accounts for ≥ 5% on a molar basis, of the active substance at the final time point.*

According to the List of Endpoints in the Assessment Report, there are three metabolites ranging from 12.6 to 17.2% in photolysis studies. However, it is not clear how much photolysis contributes to total degradation in the environment, as photolysis would be restricted to the upper zones of water bodies. Metabolites which are observed in water-sediment biodegradation studies are considered to be more certain to form in environmental conditions. The List of Endpoints in the Assessment Report indicates a single major metabolite identified as NTN33893-desnitro formed during water-sediment tests.

In a 92-day aerobic biodegradation study in the dark, 6% was observed in water and 6.3% in sediment (12.3% total system). In a 358-day anaerobic biodegradation study, a maximum of 20% of the metabolite was observed in water after 60 days and a maximum of 51.5% in sediment after 249 days (total system: max. 66% after 249 days). In a 366-day open water aerobic study in the dark, the same metabolite was observed in water at a maximum of 26.4% after 274 days, reducing to 19.2% after 366 days.

From these results it seems reasonable to take the worst-case as 26.4% in water, and 51.5% in sediment for the purpose of PEC calculations. The ECHA guidance (v.1, volume IV, part B) allows as a first step a “*semi-quantitative assessment of these metabolites using the available data and expert judgement to fill data gaps may be sufficient”.*

An approach which has been used by at least one Competent Authority is to multiply the PEC for the active by the maximum occurrence of the metabolite, and then compare this to the PNEC of the active (if no PNEC is available for the active).Therefore, a similar approach is considered appropriate here.

The calculated PECs for NTN33893-desnitro in water and sediment are shown in the table below:

Local PECs for NTN33893-desnitro in surface water compartment.

|  |  |  |  |
| --- | --- | --- | --- |
| N. | Local PEC (imidacloprid) in surface water | Maximum % occurrence of NTN33893-desnitro | Local PEC NTN33893-desnitro |
| Scenario 1 | 4.51E-06 | 26,40% | 1.19E-06 |
| Scenario 2 | negligible | 0 |
| Scenario 3 | 3.72E-06 | 9.82E-07 |
| Scenario 4 | 4.41E-06 | 1.16E-06 |
| Scenario 5 | negligible | 0 |
| Scenario 6 | 2.61E-06 | 6.89E-07 |
| Scenario 7 | negligible | 0 |

Local PECs for NTN33893-desnitro in freshwater sediment compartment.

|  |  |  |  |
| --- | --- | --- | --- |
| N. | Local PEC (imidacloprid) in freshwater sediment | Maximum % occurrence of NTN33893-desnitro | Local PEC NTN33893-desnitro |
| Scenario 1 | 2.6E-05 | 51.5% | 1,34E-05 |
| Scenario 2 | negligible | 0 |
| Scenario 3 | 2.15E-05 | 1,11E-05 |
| Scenario 4 | 2.55E-05 | 1.31E-05 |
| Scenario 5 | negligible | negligible |
| Scenario 6 | 1.51E-05 | 7,78E-06 |
| Scenario 7 | negligible | 0 |

|  |
| --- |
| Infobox 19 – FR CA position :  Only one relevant metabolite (NTN33893-desnitro) was found in the water-sediment compartment. Nevertheless, as imidacloprid metabolites were found to be very less toxic than imidacloprid (final CAR Doc- II), a risk assessment for this metabolite is considered not relevant. |

#### Risk characterisation

***Atmosphere***

Conclusion:Negligible effect to atmosphere compartment. The Biocidal Product is a bait. Active substance and co-formulants have low vapour pressure. Therefore, no risk for air compartment is expected to occur after Biocidal Product application.

***Sewage treatment plant (STP)***

**PNECSTP: 61.3mg/l**

|  |  |
| --- | --- |
| **Summary table on calculated PEC/PNEC values** | |
|  | **PEC/PNECSTP** |
| Scenario 1 | 4.51E-07 |
| Scenario 2 | 0 |
| Scenario 3 | 3.67E-07 |
| Scenario 4 | 4.41E-07 |
| Scenario 5 | 0 |
| Scenario 6 | 2.61E-07 |
| Scenario 7 | 0 |

Conclusion:

No risk for STP compartment is expected to occur after Biocidal Product application. Moreover, emission scenarios have been developed considering daily and weekly application for indoor and around/outdoor treatments constituting an over-estimation of the use of the product. Indeed DX3 Gel have been demonstrated to have a high residual activity, which per se, limits its constant and repetitive application over time. Therefore, emissions to compartment will be lower than those calculated with ESD models.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Infobox 20 – FR CA position :  We agree with the risk assessment and conclusions for the STP compartment.  Nevertheless, we would like to clarify some points on this risk assessment:   * Taking into account the technical value of imidacloprid (0.0204%) and a PNECSTP=61.3mg/L, the PEC/PNEC ratios are a little bit different from the ones proposed by the applicant. * Concerning the Scenario 1, with the exposure refinement using more appropriates cleaning efficiency and treated areas (cf. Infobox N°5), the PEC/PNEC value for the STP compartment is smaller than the one proposed by the applicant (cf table below)  |  |  | | --- | --- | | **Summary table on calculated PEC/PNEC values** | | | **Scenario N°** | **PEC/PNECSTP** | | **Indoor scenarios** | | | **1** (gel) | 2.82E-07 | | **2** (box) | Not relevant | | **Outdoor scenarios** | | | **3** (gel ; perimeter) | 6.77E-07 | | **4** (gel ; terrace; nest) | 7.34E-07 | | **5** (gel; bare soil; nest) | Not relevant | | **6** (box; terrace ; nest) | 4.35E-07 | | **7** (box; bare soil; nest) | Not relevant | |

***Aquatic compartment***

**PNECwater: 4.8E-06mg/l**

**PNECsediment: 2.6E-05 mg/kgwwt**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table on calculated PEC/PNEC values** | | | | |
|  | **PEC/PNECwater** | **PEC/PNECsed** | **PEC/PNECseawater** | **PEC/PNECseased** |
| Scenario 1 | 0.94 | 1 | / | / |
| Scenario 2 | 0 | 0 | / | / |
| Scenario 3 | 0.77 | 0.82 | / | / |
| Scenario 4 | 0.92 | 0.98 | / | / |
| Scenario 5 | 0 | 0 | / | / |
| Scenario 6 | 0.54 | 0.58 | / | / |
| Scenario 7 | 0 | 0 |  |  |

Conclusion:

No risk for aquatic compartment is expected to occur after Biocidal Product application. Indeed, the scenario n.1 refers to a worst-case scenario based on daily application by professional and therefore all the further scenarios (from number 2 to 6, although being developed considering different area of application, i.e. around building, or outdoor) lead to lower amount of active substance release to relevant environmental compartments. Moreover, scenario have been developed considering daily and weekly application for indoor and around/outdoor treatments constituting an over-estimation of the use of the product. Indeed DX3 Gel have been demonstrated to have a high residual activity which per se limit its constant and repetitive application over time. Therefore, emissions to aquatic compartments will be lower than those calculated with ESD models.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Infobox 21 – FR CA position :  We agree with the risk assessment and conclusions for the aquatic compartment (indirect release via the STP).  Nevertheless, we would like to clarify some points on this risk assessment:   * Taking into account the technical value of imidacloprid, the PEC/PNEC ratios are a little bit different from the ones proposed by the applicant. * Concerning the Scenario 1, with the exposure refinement using more appropriates cleaning efficiency and treated areas (cf. Infobox N°5), the PEC/PNEC values for the aquatic compartment are smaller than the one proposed by the applicant (cf table below)  |  |  |  | | --- | --- | --- | | **Summary table on calculated PEC/PNEC values** | | | | **Scenario N°** | **PEC/PNECwater** | **PEC/PNECsed** | | **Indoor scenarios** | | | | **1** (gel) | 0.36 | 0.38 | | **2** (box) | Not relevant | Not relevant | | **Oudoor scenarios** | | | | **3** (gel; perimeter) | 0.86 | 0.92 | | **4** (gel ; terrace; nest) | 0.94 | 0.99 | | **5** (gel ; bare soil; nest) | Not relevant | Not relevant | | **6** (box; terrace; nest) | 0.55 | 0.59 | | **7** (box; bare soil; nest) | Not relevant | Not relevant |   In conclusion, considering the product is only places outdoor in bait boxes, in cracks and crevices and in places protected from weather, releases to the STP will be minimised and risks to the aquatic compartment are considered acceptable. |

***Terrestrial compartment***

**PNECsoil: 0.01575 mg/kgwwt**

|  |  |  |
| --- | --- | --- |
| **Calculated PEC/PNEC values** | | |
|  | **PEC/PNECsoil** | |
| Scenario 1 | 3.26E-04 | |
| Scenario 2 | 0 | |
| Scenario 3 | 9.69E-03 | 3.94E-03 (bare soil) |
| Scenario 4 | 0.02 | 0.02 (bare soil) |
| Scenario 5 | 2.24E-02 | |
| Scenario 6 | 6.79E0-3 | 0.42(bare soil) |
| Scenario 7 | 1.19E-02 | |

Conclusion:

No risk for terrestrial compartment is expected to occur after Biocidal Product application. Moreover, scenario have been developed considering daily and weekly application for indoor and around/outdoor treatments constituting an over-estimation of the use of the product. Indeed DX3 Gel have been demonstrated to have a high residual activity which per se limit its constant and repetitive application over time. Therefore, emissions to terrestrial compartments (direct and indirect) will be lower than those calculated with ESD models.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Infobox 22 – FR CA position :  FR CA agrees with the risk assessment and conclusions for the terrestrial compartment.  Nevertheless, taking into account the different points from the Infoboxes above, the calculated ratios are presented below:   |  |  |  | | --- | --- | --- | | **Calculated PEC/PNEC values** | | | |  | **PEC/PNECsoil** | | | **Emission**  **Scenario N°** | **Indirect, via the STP** | **Direct release to soil** | | **Indoor scenarios** | | | | **1** (gel) | 1.36E-04 | Not relevant | | **2** (box) | Not relevant | Not relevant | | **Oudoor scenarios** | | | | **3** (gel; perimeter) | 3.26E-04 | 2.64E-03 | | **4** (gel ; terrace; nest) | 3.53E-04 | 9.68E-03 | | **5** (gel ; bare soil; nest) | Not relevant | 2.29E-02 | | **6** (box; terrace; nest) | 2.09E-04 | 5.74E-03 | | **7** (box; bare soil; nest) | Not relevant | 1.22E-02 |   All the PEC/PNEC ratios for soil are below the trigger value of 1. No risks for the terrestrial compartment are foreseen for the uses of DX3 gel. |

***Groundwater***

**PNECgw: 0.0001 mg/l**

|  |  |  |
| --- | --- | --- |
| **Calculated PEC/PNEC values** | | |
|  | **PEC/PNECsoil** | |
| Scenario 1 | 8.5E-03 | |
| Scenario 2 | 0 | |
| Scenario 3 | 2.51E-01 | 1.48E-01(bare soil) |
| Scenario 4 | 5.27E-01 | 7.16E-01 (bare soil) |
| Scenario 5 | 6.22E-01 | |
| Scenario 6 | 1.77E-01 | 0.42 (bare soil) |
| Scenario 7 | 4.51E-01 | |

Conclusion:

No risk for groundwater compartment is expected to occur after Biocidal Product application. Moreover, emission scenarios have been developed considering daily and weekly application for indoor and around/outdoor treatments constituting an over-estimation of the use of the product. Indeed DX3 Gel have been demonstrated to have a high residual activity which per se limit its constant and repetitive application over time. Therefore, emissions to groundwater (direct and indirect) will be lower than those calculated with ESD models.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Infobox 23 – FR CA position :  FR CA agrees with the risk assessment and conclusions for the groundwater.  Nevertheless, taking into account the different points from the Infobox above the calculated PEC values are presented below:   |  |  |  | | --- | --- | --- | | **Calculated PEC values** | | | |  | **PEC GW1 (µg/L)** | | | **Emission**  **Scenario N°** | **Indirect, via the STP** | **Direct release to soil** | | **Indoor scenarios** | | | | **1** (gel) | 5.12E-04 | Not relevant | | **2** (box) | Not relevant | Not relevant | | **Outdoor scenarios** | | | | **3** (gel; perimeter) | 1.23E-03 | 9.95E-03 | | **4** (gel ; terrace; nest) | 1.33E-03 | 3.65E-02 | | **5** (gel ; bare soil; nest) | Not relevant | 8.62E-02 | | **6** (box; terrace; nest) | 7.89E-04 | 2.16E-02 | | **7** (box; bare soil; nest) | Not relevant | 4.60E-02 | | 1 *Calculated as: PECsoil initial \* RHOsoil/ (ksoil-water \* 1000); eq67 Guidance on the Biocidal Products Regulation, Volume IV Environment - Assessment and Evaluation (Parts B + C)* | | |   All the PEC values for groundwater are below the trigger value of 0.1 µg/L. No risks for groundwater are foreseen for the uses of DX3 gel. |

***Primary and secondary poisoning***

Conclusion:

No risk for primary poisoning is expected: according to OECD emission scenario for PT18 “it is not believed that powder, gels, or any sort of insecticides are in a form that could be sufficiently appetent to bird or mammals so they would be at risk”.

No risk for secondary poisoning is expected for fish (aquatic food chain) and earthworm (terrestrial food chain) eating predator based on the calculated PECs. Indeed, according to data in the CAR of Imidacloprid active substance, PNEC oral is 0.31 mg/kg bw/d for birds. According to EUSES calculation the RCR ratios are:

Fish RCR: 2.29E-08

Worm RCR: 1.31E-07

No risk for primary and secondary poisoning is expected to occur after Biocidal Product application.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Infobox 24 – FR CA position : **Bees assessment:**  FR CA does not agree with the risk assessment and conclusions for the bees proposed by the applicant (cf. Infobox N°18).  Considering the high level of risk for bees, when used outdoors, the product must be used in pre-filled bait boxes to protect from non-target organisms . When this is not practically possible, crack and crevice gel applications are also permitted in order to minimize access from non-target organisms. With respect to the condition of outdoor uses, the risk for bees can be considered as negligible. The following RMM have been added by the FR CA:   * “For outdoor use, apply this biocidal product in bait boxes or in cracks and crevices only or directly to ant nests. Protect from bees and the weather by covering, for example with a flowerpot or a tile (ensuring that the ants still get access to the bait)”.   **Secondary poisoning:**  FR CA agrees with the risk assessment and conclusions for the secondary poisoning.  Nevertheless, taking into account the different points from the Infoboxes above, the calculated ratios are presented below:   |  |  |  |  | | --- | --- | --- | --- | | **Summary table on calculated PEC values** | | | | | Scenario N° | Receiving compartment | **PECFISH /PNECBIRD** | **PECEARTHWORM/PNEC BIRD** | | **Indoor scenarios** | | | | | **1** (gel) | STP | 2.78E-06 | 7.95E-08 | | **2** (box) | Not relevant | Not relevant | Not relevant | | **Outdoor scenarios** | | | | | **3** (gel; perimeter) | STP | 3.01E-07 | 1.94E-07 | | Soil | Not relevant | 1.54E-06 | | **4** (gel; terrace; nest) | STP | 3.26E-07 | 2.07E-07 | | Soil | Not relevant | 5.67E-06 | | **5** (gel; bare soil; nest) | Soil | Not relevant | 3.01E-05 | | **6** (box; terrace; nest) | STP | 1.93E-07 | 1.22E-07 | | Soil | Not relevant | 3.36E-06 | | **7 (**box; bare soil; nest) | Soil | Not relevant | 1.60E-05 | |

***Risk from metabolites***

No major metabolites were observed in soil metabolism studies.

One major metabolite from water-sediment studies was identified in the Assessment Report; NTN33893-desnitro.

A long-term study with Chironomus riparius produced a 28d-EC10 of 9.45 mg/L This indicates that the metabolite is orders of magnitude less toxic than the parent substance imidacloprid. Therefore, the derivation of a PNECwater for this metabolite is not required (ref: Assessment Report).

For the purpose of this risk assessment, if the PNECs used for the active are also used for comparison with the metabolite PECs, this will represent an extreme worst-case PEC/PNEC.

1. PEC/PNEC for NTN33893-desnitro in surface water compartment.

|  |  |  |  |
| --- | --- | --- | --- |
| N. | Local PEC (metabolite) in surface water | PNECs for imidacloprid (mg/L) | PECmetabolite/PNECimid |
| Scenario 1 | 1.19E-06 | 4,80E-06 | 2.48E-01 |
| Scenario 3 | 9.82E-07 | 2.05E-01 |
| Scenario 4 | 1.16E-06 | 0.24 |
| Scenario 6 | 6.89E-07 | 0.14 |
| \*Scenarios with negligible emission are not considered | | | |

PEC/PNEC for NTN33893-desnitro in freshwater sediment compartment.

|  |  |  |  |
| --- | --- | --- | --- |
| N. | Local PEC (metabolite) in freshwater sediment | PNECs for imidacloprid (mg/kg wwt) | PECmetabolite/PNECimid |
| Scenario 1 | 1.34E-05 | 2,60E-05 | 5.15E-01 |
| Scenario 3 | 1.11E-05 | 4.26E-01 |
| Scenario 4 | 1.31E-05 | 5.05E-01 |
| Scenario 6 | 7.78E-06 | 2.99E-01 |
| \*Scenarios with negligible emission are not considered | | | |

**Conclusion**

There is no concern in the aquatic compartment for the main metabolite identified. Risks to other compartments are considered negligible.

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| Infobox 25 – FR CA position :  As said in Infobox N°19, it is not relevant to perform an environmental risk assessment for the imidacloprid metabolites. |

***Mixture toxicity***

There is no relevant mixture toxicity to take into account.

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| **Overall conclusion on the risk assessment for the environment of the product** |
| No intrinsic hazardous physic-chemical properties of the biocidal product have been identified.  The AEL% and PEC/PNEC ratios indicate that there is no concern to the human/animal health or to the environment from the proposed use of DX3 GEL.  There is at present no need for further information and/or testing or for risk reduction measures beyond those stated on the label used for the product. |

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| Infobox 26 – FR CA position :  FR CA agrees with the applicant argumentation. |

***Aggregated exposure (combined for relevant emission sources)***

Considering that:

- guidelines to conduct an aggregated exposure assessment are still under development as cited at page 207 of Guidance on the Biocidal Products Regulation Volume IV Environment - Assessment and Evaluation (Parts B + C) Version 2.0 October 2017;

- the active substance Imidacloprid, is approved for use in products only within a single product type (PT18) under BPR;

- the active substance Imidacloprid, although approved also under PPPR, it does not share the same emission pattern as the biocidal emission pattern;

it is extremely unrealistic that an overlap in time and space between different uses (BPR and PPPR) and user categories (professionals and non-professionals) may occur on a daily basis in the same exposed area.



*Figure 1: Decision tree on the need for estimation of aggregated exposure*

Conclusion: On the basis of the lack of a specific guidance and on the basis of the consideration mentioned above, no aggregated exposure assessment is deemed necessary for this biocidal product. A qualitative assessment is deemed sufficient to conclude that no overlap in time and space for the simultaneous use of the product and its active substance will occur on a regular (daily) basis.

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| Infobox 27 – FR CA position:  FR CA agrees with the applicant argumentation. Moreover, taking into account the authorised uses by FR CA and the RMM (outdoor application restricted to bait boxes, cracks and crevices and places protected from rainfall), emissions sources from outdoor and indoor uses are not expected to cumulate in the STP compartment. |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Infobox 28 – FR CA CONCLUSION FOR THE ENVIRONNEMENT ASSESSMENT :  FR CA concludes the product DX3gel poses no risk to the terrestrial or aquatic environmental compartments for indoor and outdoor uses, whether for bait-boxes or gel drops, taking into account the intended application rate and the uses recommendations.  Nevertheless, the product contains the active substance Imidacloprid known to be toxic to bees and therefore a risk for bees cannot be excluded.  For these reasons, when used outdoors, the product must be pre-filled bait boxes to protect from bees. When this is not practically possible, crack and crevice applications are also permitted in order to minimize access from non-target organisms. With respect to the condition of outdoor uses, honeybee exposure can be considered as negligible. The following RMM has been added by the FR CA:   * “For outdoor use, apply this biocidal product in bait boxes or in cracks and crevices only or directly to ant nests. Protect from bees and the weather by covering, for example with a flowerpot or a tile (ensuring that the ants still get access to the bait)”.   Overall conclusion on the risk assessment for the environment of the product is summarized in the table bellow:   |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | | Summary table for the risk assessment of the product Insecticides for home use | | | | | | | | Scenario N° | Emission | PEC/PNECstp | PEC/PNECwater | PEC/PNECsed | PEC/PNECsoil | PEC/PNECGW | | **Indoor** | | | | | | | | **1** (gel) | STP | Acceptable | Acceptable | Acceptable | Acceptable | Acceptable | | **2** (box) | Not relevant | Not relevant | Not relevant | Not relevant | Not relevant | Not relevant | | **Oudoor** | | | | | | | | **3** (gel; perimeter) | STP | Acceptable | Acceptable | Acceptable | Acceptable | Acceptable | | Soil | Not relevant | Not relevant | Not relevant | Acceptable | Acceptable | | **4** (gel ; terrace; nest) | STP | Acceptable | Acceptable | Acceptable | Acceptable | Acceptable | | Soil | Not relevant | Not relevant | Not relevant | Acceptable | Acceptable | | **5** (gel ; bare soil; nest) | Soil | Not relevant | Not relevant | Not relevant | Acceptable | Acceptable | | **6** (box; terrace; nest) | STP | Acceptable | Acceptable | Acceptable | Acceptable | Acceptable | | Soil | Not relevant | Not relevant | Not relevant | Acceptable | Acceptable | | **7** (box; bare soil; nest) | Soil | Not relevant | Not relevant | Not relevant | Acceptable | Acceptable | |

### Measures to protect man, animals and the environment

### Assessment of a combination of biocidal products

The biocidal products is not intended to be authorised for the use with other biocidal products.

### Comparative assessment

According to the most recent scientific information available on the active substance in the biocidal product, the insecticide (PT18) imidacloprid shall be considered as a candidate for substitution using the criteria in the regulation (UE) 528/2012, Article 10(1). Imidacloprid is considered to be persistent/very persistent (P/vP) and toxic (T) but not bio-accumulative in accordance with the criteria laid down in Annex XIII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council. It meets two of the criteria for being PBT in accordance with Annex XIII to the regulation (EC) No 1907/2006. Imidacloprid does not meet the exclusion criteria laid down in Article 5 of Regulation (EU) No 528/2012.

Under Article 23(1) of Regulation 528/2012, Member States evaluating biocidal product containing at least, one active substance that is a candidate for substitution in accordance with Article 10(1) are required to perform a comparative assessment. FR CA has performed it for the biocidal product DX3 GEL following the EU guidance[[6]](#footnote-7).

The biocidal product DX3 GEL is an insecticide product containing one active substance which imidacloprid, meets the criteria for substitution under Article 10 of the Biocidal Products Regulation (528/2012).

In line with the Note for Guidance, FR CA began the comparative assessment with the screening phase (Annex 1.1 of guidance document) to identify whether the diversity of the active substances - mode of action combination in authorised biocidal products is adequate.

The full comparative assessment is available in a separate confidential document.

# Overall conclusion

In the technical guidance note on comparative assessment of biocidal products, it is stated that :

* a suitable number of available active substances having different modes of action on the harmful organism would be necessary to minimise resistance development or selection ;
* as a general rule, at least three different and independent “active substance/mode of action” combinations should remain available through authorized BPs for a given use in order to consider that chemical diversity is adequate.

Considering that only a few number of products with different active substance / mode of action have been identified as potential alternatives for each uses of DX3 GEL, FR CA concludes that there is no an adequate chemical diversity in line with Article 23(3)(b) and the technical guidance note on comparative assessment.

Since imidacloprid does not meet the exclusion criteria as outlined in Article 5(1), no further assessment is needed at this point.

**The authorization for the product DX3 GEL can be granted in accordance with the BPR 528/2012.**

# Annexes[[7]](#footnote-8)

## List of studies for the biocidal product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Author(s)** | **Year** | **Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published** | **Data Protection Claimed (Yes/No)** | **Owner (PUB / ORG)** | **Date of first submission** |
| Urbani M. | 2017 | DX3 gel bait: Determination of the Physico-chemical Properties. Chemservice, CH585/2017. GLP (unpublished) | YES | ZAPI S.p.A. | 09/04/2018 |
| Urbani M. | 2017 | DX3 gel bait: Validation of the Analytical Method for the Determination of the Active Ingredient Content. Chemservice, CH586/2017. GLP (unpublished) | YES | ZAPI S.p.A. | 09/04/2018 |
| Urbani M. | 2017 | DX3 gel bait: Determination of the Accelerated Storage Stability and Corrosion Characteristics. Chemservice, CH587/2017. GLP (unpublished) | YES | ZAPI S.p.A. | 09/04/2018 |
| Urbani M. | 2017 | DX3 gel bait: Determination of the Accelerated Storage Stability and Corrosion Characteristics. Chemservice, CH588/2017. GLP (unpublished) | YES | ZAPI S.p.A. | 09/04/2018 |
| Urbani M. | 2017 | DX3 gel bait: Determination of the Accelerated Storage Stability and Corrosion Characteristics. Chemservice, CH589/2017. GLP (unpublished) | YES | ZAPI S.p.A. | 09/04/2018 |
| Urbani M. | 2017 | DX3 gel bait: Determination of the Accelerated Storage Stability and Corrosion Characteristics. Chemservice, CH678/2017. GLP (unpublished) | YES | ZAPI S.p.A. | 09/04/2018 |
| Urbani M. | 2018 | DX3 gel bait: Determination of the Accelerated Storage Stability and Corrosion Characteristics. Chemservice, CH042/2018. GLP (unpublished) | YES | ZAPI S.p.A. | 09/04/2018 |
| Urbani M. | 2018 | DX3 gel bait: Determination of the Accelerated Storage Stability and Corrosion Characteristics. Chemservice, CH045/2018. GLP (unpublished) | YES | ZAPI S.p.A. | 09/04/2018 |
| Serrano B. | 2017 | SIMULATED USE TRIAL OF THE EFFICACY OF AN INSECTICIDAL GEL BAIT INTENDED TO CONTROL ANTS. T.E.C. Laboratory, 2203-GEL-FRESH-SIM-LN/0317. Unpublished. | YES | ZAPI S.p.A. | 09/04/2018 |
| Serrano B. | 2017 | SIMULATED USE TRIAL OF THE EFFICACY OF AN INSECTICIDAL GEL BAIT INTENDED TO CONTROL ANTS. T.E.C. Laboratory, 2203-GEL-AGED3M-SIM-LN/0317. Unpublished. | YES | ZAPI S.p.A. | 09/04/2018 |
| Serrano B. | 2017 | SIMULATED USE TRIAL OF THE EFFICACY OF AN INSECTICIDAL GEL BAIT INTENDED TO CONTROL ANTS. T.E.C. Laboratory, 2203-GEL-AGED3Y-SIM-LN/0317. Unpublished. | YES | ZAPI S.p.A. | 09/04/2018 |
| Serrano B. | 2017 | FIELD ASSESSMENT OF THE EFFICACY OF AN INSECTICIDAL GEL BAIT AGAINST ANTS. T.E.C. Laboratory, 2203-GEL-FIELD-LN/0317. Unpublished. | YES | ZAPI S.p.A. | 09/04/2018 |
| Serrano B. | 2016 | SIMULATED USE TRIAL OF THE EFFICACY OF AN INSECTICIDAL GEL BAIT INTENDED TO CONTROL ARGENTINE ANTS  *Linepithema humile.* T.E.C. Laboratory, 2120a/0716. Unpublished. | YES | ZAPI S.p.A. | 09/04/2018 |
| Serrano B. | 2017 | SIMULATED USE TRIAL OF THE EFFICACY OF AN INSECTICIDAL GEL BAIT INTENDED TO CONTROL ANTS. T.E.C. Laboratory, 2203-GEL-AGED3M-SIM-LH/0317. Unpublished. | YES | ZAPI S.p.A. | 09/04/2018 |
| Serrano B. | 2017 | SIMULATED USE TRIAL OF THE EFFICACY OF AN INSECTICIDAL GEL BAIT INTENDED TO CONTROL ANTS. T.E.C. Laboratory, 2203-GEL-AGED3Y-SIM-LH/0317. Unpublished. | YES | ZAPI S.p.A. | 09/04/2018 |
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| Serrano B. | 2017 | FIELD ASSESSMENT OF THE EFFICACY OF INSECTICIDAL BAITS AGAINST ARGENTINE ANTS. T.E.C. Laboratory, 2203-BOX-FIELD-LN/0317. Unpublished. | YES | ZAPI S.p.A. | 09/04/2018 |

## Output tables from exposure assessment tools



## Summaries of the efficacy studies (B.5.10.1-xx)[[8]](#footnote-9)

| **Test substance** | **Test organisms** | **Test system / Concentrations applied / exposure time** | **Test conditions** | **Test results: effects, mode of action, resistance** | **Reference** | **RI** |
| --- | --- | --- | --- | --- | --- | --- |
| Serrano B. | 2017 | SIMULATED USE TRIAL OF THE EFFICACY OF AN INSECTICIDAL GEL BAIT INTENDED TO CONTROL ANTS. T.E.C. Laboratory, 2203-GEL-FRESH-SIM-LN/0317. Unpublished. | YES | ZAPI S.p.A. | 09/04/2018 | RI :1 |
| Serrano B. | 2017 | SIMULATED USE TRIAL OF THE EFFICACY OF AN INSECTICIDAL GEL BAIT INTENDED TO CONTROL ANTS. T.E.C. Laboratory, 2203-GEL-AGED3M-SIM-LN/0317. Unpublished. | YES | ZAPI S.p.A. | 09/04/2018 | RI :1 |
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| Serrano B. | 2016 | SIMULATED USE TRIAL OF THE EFFICACY OF AN INSECTICIDAL GEL BAIT INTENDED TO CONTROL ARGENTINE ANTS  *Linepithema humile.* T.E.C. Laboratory, 2120a/0716. Unpublished. | YES | ZAPI S.p.A. | 09/04/2018 | RI :1 |
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| Serrano B. | 2017 | FIELD ASSESSMENT OF THE EFFICACY OF INSECTICIDAL BAITS AGAINST ARGENTINE ANTS. T.E.C. Laboratory, 2203-BOX-FIELD-LN/0317. Unpublished. | YES | ZAPI S.p.A. | 09/04/2018 | RI :1 |

## Confidential annex

Please refer to the confidential annex document

1. Please fill in here the identifying product name from R4BP. [↑](#footnote-ref-2)
2. Please delete as appropriate. [↑](#footnote-ref-3)
3. For micro-organisms based products: indication on the need for the biocidal product to carry the biohazard sign specified in Annex II to Directive 2000/54/EC (Biological Agents at Work). [↑](#footnote-ref-4)
4. Describe the necessary instructions for use like for example: period of time needed for the biocidal effect; the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by humans or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during transport; precautions to be taken to avoid the development of resistance. [↑](#footnote-ref-5)
5. Efficacy trials method for bait insecticide products intended to control ants [↑](#footnote-ref-6)
6. Notes for guidance: Comparative assessment of biocidal products – Consolidated version of CA Sept13-Doc.5.1.f & CA-Dec13-Doc5.1.k-Final: Ca-March14-Doc.5.4 [↑](#footnote-ref-7)
7. When an annex in not relevant, please do not delete the title, but indicate the reason why the annex should not be included. [↑](#footnote-ref-8)
8. If an IUCLID file is not available, please indicate here the summaries of the efficacy studies. [↑](#footnote-ref-9)